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Dietary risk factors and therapy outcomes of swallowing-related problems in laryngopharyngeal reflux: patients' perspectives



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Abstract

Background: This was a prospective cohort that included 60 gastro-esophageal reflux disorder patients with suspected laryngopharyngeal reflux-related symptoms (e.g., sore throat, throat clearing, globus sensation, cough, dysphonia, and dysphagia). The diagnosis was confirmed using history taking, clinical laryngoscopic examination, and upper endoscopy guided by the Reflux Symptom Index (RSI). Patients were treated with proton pump inhibitors and prokinetics for 12 weeks. The aim of the current study was to explore the dietary risk factors in laryngopharyngeal reflux patients and to assess the response to therapy on swallowing-related problems by comparing the baseline pre-treatment and post-treatment values of RSI and Dysphagia Handicap index (DHI).

Results: Analysis of data regarding the role of diet as a risk factor for reflux revealed that 33 patients (55%) are eating meat, 56 patients (93.3%) eating fat, 45 patients (75%) eating sweet, 55 patients (91.7%) eating spicy food, 52 patients (96.7%) eating fried food, 34 patients (56.7%) drinking tea, 51 patients (85%) eating big meals, 21 patients (35%) drinking fruit juices, 54 patients (90%) eating sour foods, 51 patients (85%) eating citrus fruits, and 22 patients (36.7%) smokers. There was a statistically significant decrease in Reflux Symptom Index scores and an increase of Dysphagia Handicap Index scores after 12 weeks on proton pump inhibitors and prokinetics.

Conclusion: Different dietary factors were present in LPR patients. A short period of empiric anti-reflux treatment has a significant improving effect on Reflux Symptom Index and Dysphagia Handicap Index scores from baseline to 12 weeks post-treatment. Further research is needed to investigate longer times of treatment for the complete resolution of symptoms.

Keywords: Laryngopharyngeal reflux, Swallowing problems, Risk factors, Treatment

Background

Laryngopharyngeal reflux (LPR) is an otolaryngological and gastrointestinal condition in which retrograde flow of gastric contents to the laryngopharynx occurs [1]. LPR is considered the extra-esophageal manifestations of

gastro-esophageal reflux disorder (GERD) [2] which include dysphonia, laryngospasm, vocal fatigue, excessive throat clearing, globus pharyngeus, chronic cough, postnasal drip, and dysphagia [3, 4]. It should be emphasized that the diagnosis of LPR is difficult due to atypical symptoms and related factors, such as smoking, infection, allergy, and poor voice hygiene [5, 6].

Several controversies were concerned regarding LPR diagnosis. Laryngoscopic findings may include erythema, edema, ventricular obliteration, post-cricoid hyperplasia,

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and pseudosulcus. The previous findings are not specific and can be found in healthy individuals [6, 7].

The reliability of 24-h dual-probe pH monitoring is debatable because it cannot be performed in all LPR patients due to their invasiveness, lower sensitivity, and high cost [8].

As there is no gold standard for the diagnosis of LPR [9], patient reports have become a primary method to diagnose LPR and monitor treatment outcomes [10, 11]. Many clinicians rely on symptomatology evaluation and empirical treatment with proton pump inhibitors (PPIs) for patients with LPR [5, 12].

Nowadays, the most widely used patient-reported questionnaire is the Reflux Symptom Index (RSI) which focuses on laryngeal findings [13] and has shown high sensitivity when detecting LPR [8, 14]. In addition, Dysphagia Handicap Index (DHI), a 25-item self-administered questionnaire, has been developed as an indicator for handicapping effect of dysphagia on the physical, functional, and emotional aspects of lives. It provides vital information to the clinician concerning the success or failure of therapy [15].

Many differences were found in drug, dose, and duration of medical treatment of LPR. An optimal therapeutic protocol is based on PPIs [16, 17]. Many studies showed the superiority of PPIs and prokinetics over PPIs [18–20]. A potential association was found between long-term PPI therapy and the occurrence of side effects [1, 21] such as pneumonia, *Clostridium difficile* diarrhea, and reduced calcium absorption [22–24].

With large referral rates of LPR patients with reflux-related swallowing problems to the Phoniatrics clinic, the need to provide such a protocol for treatment, and follow-up from Phoniatrics prospective increased. Therefore, the purpose of the current study was to explore the dietary risk factors in laryngopharyngeal reflux patients and to assess the response of 12 weeks of therapy by PPIs and prokinetics on self-perception of swallowing-related problems in LPR patients. The therapy outcome was assessed by comparing the baseline pre-treatment and post-treatment values of RSI and DHI.

Methods

Subjects

This study was conducted in the period between January 2019 and June 2019. The current study was approved by the Institutional Review Board of Faculty of Medicine, Egypt, Approval No: FMBSUREC/01092020/Atta. All patients signed a written informed consent form before entering the study.

The study included 60 adult male and female GERD patients complaining of LPR symptoms. Cases were selected from the Gastrointestinal Endoscopy Unit and

referred to the Phoniatrics unit. GERD patients were complaining of symptoms suggestive of laryngopharyngeal reflux (LPR) for at least two consecutive months (dysphonia, laryngospasm, vocal fatigue, excessive throat clearing, globus pharyngeus, chronic cough, postnasal drip, and dysphagia). The exclusion criteria were as follows: patients who were on current use of anti-reflux treatment to avoid false lower scores; pregnancy; patients diagnosed by dysphagia due to other causes (neurological or psychiatric illness), previous history of neck surgery or trauma; malignancy; history of ear, nose, and throat (ENT) radiotherapy and active asthma; and uncooperative or cognitive impaired patients. Participants who gave RSI score less than 13 were excluded.

Procedure

Patient interview, history taking, and general, otolaryngeal, and neurological evaluation

Participants completed a closed-ended interview questionnaire (yes or no) about their own dietary habits (eating 1-2 meals a day, eating fatty products, eating sweets, eating spicy products, eating fried products, drinking peppermint infusion, eating one big meal in the evening, drinking fruit juices, eating sour product, eating fruits, drinking alcohol, and smoking). The questionnaire was based on previous studies on risk factors experienced in patients with GERD [25]. First, the questionnaire was translated into Arabic by expert translators then sent to researchers and professionals from medical backgrounds (physicians and academia) to give their expert opinion with respect to its simplicity. Second, a pilot study was conducted by asking the questions to a small sample of GERD patients (N = 15) for their understanding to make the questionnaire simpler and shorter regarding their response. We collected the final corrections of the questionnaire made by researchers and professionals in one model that was administered to the patients. Reliability was calculated using SPSS version 25 (IBM Corp., Armonk, NY, USA), and Cronbach's alpha was 0.87 for the total score. The data from the pilot study were not used in the final analysis.

Upper GIT endoscopy

The diagnosis of GERD was confirmed using upper GIT endoscopy. Olympus Evis CV 100 Videoscope (Olympus, Japan) was used in the endoscopy unit.

Steps of upper gastrointestinal endoscopy:

Patients were asked to be fasting for 6–8 h before endoscopy. Sedation done using midazolam (Medathetic 5 mg/ml) was administered (starting dose was 0.5–2 mg administered intravenously (IV)). Patients were monitored throughout the procedure by pulse oximetry and heart rate and blood pressure

- recording. ECG monitoring was done in patients with cardiopulmonary disease.
- Patients were placed in the left lateral position. A bite block was placed to prevent damage to the endoscope.
- Under direct vision, the endoscope was passed through the pharynx, esophagus, and stomach and into the duodenum, with careful inspection upon both insertion and slow withdrawal. Air was insufflated to distend the lumen to aid in viewing.
- Results of upper GI endoscopy were recorded for the following: edema, erythema, friability, granularity and red streaks, the presence of ulceration, masses, esophageal strictures, incompetence of cardia, hiatus hernia, and biliary reflux. Endoscopic evidence of GERD included the presence of esophageal mucosal edema, erythema, friability, mucosal breaks, ulceration, strictures of esophagus, or Barrett's esophagus.

The Los Angeles classifications of esophagitis [26]: Grade: Description

A: One (or more) mucosal break < 5 mm that does not extend between the tops of 2 mucosal folds B: One (or more) mucosal break ≥ 5 mm that does not extend between the tops of 2 mucosal folds

C: One (or more) mucosal break that is continuous between the tops of two or more mucosal folds but that involves < 75% of the circumference

D: One (or more) mucosal break that involves \geq 75% of the esophageal circumference

Post-procedure, patients were transferred to a recovery room. Once alert (after ~ 1 h), the patient was allowed to leave.

Clinical laryngoscopic examination (CLE)

All participants were examined with a flexible nasopharyngoscope (Laryngo fiberscope, with a length of 30 cm and diameter of 3.5 mm KARL STORZ GmbH & Co. KG, Tuttlingen, Germany, 11101RP) for assessment of vocal fold structure, configuration, gross mobility, posterior larynx, arytenoids and interarytenoid area, and exclusion of malignancies.

Reflux Symptom Index (RSI) (Arabic version) [27]

All patients in the study were instructed to fill out the 9-item RSI on a rating scale ranging from 0 to 5, where 0 means no problems and 5 means a severe problem. It is a noninvasive tool with the purpose of assessing the symptoms of laryngopharyngeal reflux (LPR). All participants gave RSI scores greater than 13.

Dysphagia Handicap Index (DHI) (Arabic version) [28]

The DHI is a 25-item questionnaire that is divided into subscales of physical (9 items), emotional (7 items), and

functional problems (9 items) for measuring the handicapping effect of dysphagia on the patient's life. Respondents replied precisely according to their current condition according to the following rating "0 for never, 2 for sometimes, and 4 for always" to each statement and rated their overall self-perceived dysphagia severity on a 7-point equal-appearing interval scale, given that 1 refers to normal or no problem while 7 refers to a severe problem.

Treatment

Patients were treated with a treatment scheme, including diet such as avoiding fats, alcohol, acidic foods, caffeine, chocolate, spicy foods, and late-night meals. Patients were recommended to eat at least 3 meals a day, behavioral changes, and the use of medical treatment in the form of proton pump inhibitors (Omerprazole 40 mg once daily 1 h before breakfast) and prokinetic drugs (Itopride 50 mg tab 3 times a day before meals). The respect of diet and medication was carefully assessed post-treatment through a structured follow-up. RSI and DHI had been used to assess the symptoms of laryngopharyngeal reflux (LPR) and the handicapping effect of dysphagia, respectively.

Statistical analysis

The statistical analysis of this study is conducted using the SPSS program (Statistical Package for Social Sciences) version 22. The statistical work included two stages: (1) Descriptive statistics for describing sample observations (for categorical variables, frequencies and percentages; quantitative variables are described using sample mean and standard deviations). Clustered bar charts were used for better visualization of some results. (2) Analytical part: the Shapiro test of normality was used to test if the data were normally distributed or not. If the data were normally distributed, a T-test for two independent samples was used to test the equality of means between two independent groups. If the data was not normally distributed, the Mann-Whitney test, Wilcoxon test, Spearman correlation coefficient, and Kruskal-Wallis test were used. The significance of the results was assessed in the form of a P-value that was differentiated into non-significant when P-value > 0.05 and significant when a P-value ≤0.05. Power of sample size was calculated using g*power software based on an effect size of 0.5, overall type I error rate (α) \leq 0.05, and 60 subjects expected to achieve a power of more than 80%.

Results

The study population

The study included 60 subjects in the age range between 25 and 55 years old with a mean age of 44.4 ± 6.65 years

old. Twenty-four males and 36 females participated in the study. Based on history, clinical examination, and upper GIT endoscopy, all participants were diagnosed with LPR disorder on top of GERD. Table 1 shows the age and gender distribution of the study subjects.

Dietary risk factors for reflux

As shown in Table 2, the analysis of data regarding the role of diet as a risk factor for reflux revealed that 33 patients (55%) are eating meat, 56 patients (93.3%) eating fat, 45 patients (75%) eating sweet, 55 patients (91.7%) eating spicy food, 52 patients (96.7%) eating fried food, 34 patients (56.7%) drinking tea, 51 patients (85%) eating big meals, 21 patients (35%) drinking fruit juices, 54 patients (90%) eating sour foods, 51 patients (85%) eating citrus fruits, and 22 patients (36.7%) smokers.

RSI before and after medical treatment

As shown in Table 3, analysis of data concerning RSI items before and after medical treatment, it was clear that the distribution after medical treatment was lower than that before the medical treatment. This difference was highly significant for all individual items (< 0.001).

Association between the severity of swallowing and RSI, and DHI scores

As demonstrated in Table 4, for the severity of swallowing, the results show that 85% of the sample has a moderate problem before the medical treatment, while it is only 20% after the medical treatment. No one in the sample has a severe problem after the medical treatment.

For the RSI according to the severity of swallowing, the results show significant differences between the average scores of RSI before and after treatment. For example, the average of RSI for those who have moderate severity of swallowing before the medical treatment is 14.78 while it is 11.75 after the medical treatment.

We can get the same conclusion concerning DHI and its subscales according to the severity of swallowing. For example, the average DHI for those who have moderate severity of swallowing is 49.75 before the medical treatment while it is only 33 after the medical treatment.

Table 1 Demographic data of the participants

Sociodemographic characteristics	Frequency	%
Gender		
Female	36	60
Male	24	40
Age (mean ± SD)	44. 48 ± 6.67	

Table 2 Sample distribution according to dietary risk factors for reflux

Factor	Yes		No	
	n	%	n	%
Eating 1–2 meals a day	33	55	27	45
Eating fatty products	56	93.3	4	6.7
Eating sweets	45	75	15	25
Eating spicy products	55	91.7	5	8.3
Eating fried products	52	86.2	8	13.3
Drinking peppermint infusion	34	56.7	26	43.3
Eating one big meal in the evening	51	85	9	15
Drinking fruit juices	21	35	39	65
Eating sour product	54	90	6	10
Eating fruits	43	71.7	17	28.3
Drinking alcohol	0	0	60	100
Smoking	22	36.7	38	63.3

Self-perception and therapeutic response

Significant results were obtained comparing the patient population before and after medical treatment for each parameter reported in Table 5. Statistical analysis revealed highly significant in the severity of swallowing, RSI, and A-DHI scores after medical treatment compared with before medical treatment.

Correlation between overall severity of swallowing and the RSI and DHI before and after treatment

As shown in Table 6, there is a highly statistically significant positive correlation between the overall severity of swallowing and RSI. This relation was higher before medical treatment than after the treatment.

Concerning the correlation between A-DHI and overall severity of swallowing, a significant positive relation was found between total DHI and overall severity of swallowing. This relationship was higher after medical treatment compared to before the medical treatment. It is worth noting that the relation between the overall severity of swallowing and functional A-DHI is weak and not statistically significant.

Discussion

The current work incorporates the use of the RSI and DHI for monitoring the therapy outcomes of swallowing-related problems in LPR patients from patients' perspectives. The patient response to 3 months of treatment with PPI and prokinetics resulted in a significant improvement in findings in this cohort. RSI scores before treatment were significantly higher compared to post-treatment results. Post-treatment DHI scores were significantly higher compared to pre-treatment scores. This suggests that LPR negatively affects both RSI and

Table 3 Distribution of RSI items before and after medical treatment among the participants

Items		Before medical treatment					After medical treatment					Wilcoxon	P value					
					0	1	2	3	4	5	0	1	2	3	4	5	test	
Hoarseness or a problem with your voice	n	32	23	4	1	0	0	50	10	0	0	0	0	-4.52	0.00			
	%	53.3	38.3	6.7	1.7	0	0	83.3	16.7	0	0	0	0					
Clearing your throat	n	2	24	27	7	0	0	17	38	4	1	0	0	-6.66	0.00			
	%	3.3	40	45	11.7	0	0	28.3	63.3	6.7	1.7	0	0					
Excess throat mucus or postnasal drip	n	2	24	28	6	0	0	22	34	3	1	0	0	-6.83	0.00			
	%	3.3	40	46.7	10	0	0	36.7	56.7	5	1.7	0	0					
Difficulty swallowing food, liquids, or pills	n	0	0	3	7	28	22	1	6	28	16	9	0	-6.7	0.00			
	%	0	0	5	11.7	46.7	36.7	1.7	10	46.7	26.7	15	0					
Coughing after you ate or after lying down	n	10	34	14	2	0	0	32	24	4	0	0	0	-5.54	0.00			
	%	16.7	56.7	23.3	3.3	0	0	53.3	40	6.7	0	0	0					
Breathing difficulties or choking episodes	n	12	35	12	1	0	0	33	24	3	0	0	0	-5.48	0.00			
	%	20	58.3	20	1.7	0	0	55	40	5	0	0	0					
Troublesome or annoying cough	n	15	31	12	2	0	0	35	23	2	0	0	0	-5.23	0.00			
	%	25	51.7	20	3.3	0	0	58.3	38.3	3.3	0	0	0					
Sensations of something sticking in your	n	2	24	29	4	1	0	18	37	5	0	0	0	-6.49	0.00			
throat or a lump in your throat	%	3.3	40	48.3	6.7	1.7	0	30	61.7	8.3	0	0	0					
Heartburn, chest pain, indigestion, or	n	0	14	22	16	8	0	4	39	13	2	1	1	-5.54	0.00			
stomach acid coming up	%	0	23.3	36.7	26.7	13.3	0	6.7	65	21.7	3.3	1.7	1.7					

0 means no problems and 5 means a severe problem

P>0.05: Non-significant (NS), P< 0.05: Significant (S), P<0.01: Highly significant (HS)

DHI ratings. These results assume the significant influence of PPI treatment on LPR patients' self-perception of reflux symptoms and quality of life, respectively. Our findings agree with the previous findings assessing the quality of life in patients with LPR [29, 30].

The positive correlation reported between the overall severity of swallowing and the DHI scores and RSI before and after treatment emphasizes the positive influence of PPI therapy on patients' self-perception of swallowing problems.

Our results coincide with a study [30] in LPR patients diagnosed by pH monitoring, which reported a positive correlation between DHI, RSI, and the pH monitoring results. The study also showed a significant positive

correlation between the overall feeling of swallowing difficulty with the RSI scores and pH monitoring results. They signify that apart from sophisticated dysphagia assessment tools, the general feeling of swallowing difficulty is also negatively affected by LPR, which in turn affects patient quality of life. Their study was limited to baseline assessment with no medical treatment or follow-up.

In accordance with our results, previous findings of Aviv et al. [31] revealed that treatment of LPR with proton pump inhibitors significantly reduced the number of aspiration and penetration events. Also, they attributed the swallowing problems in LPR patients to the anatomical and physiological changes in the hypopharynx.

Table 4 RSI and DHI by severity of swallowing before and after medical treatment

		Before medical treatment				After medical treatment					
		Normal	Moderate	Severe	Kruskal-	P value	Normal	Moderate	Severe	Mann-	P value
Severity of	n	 3	51	6	Wallis test		48	12	0	Whitney test	
swallow	%	5	85	10	test		80	20	0	test	
RSI		8.33 ± 2.51	14.78 ± 4.1	21.3 ± 3.1	15.8	0.00	6.81 ± 3.9	11.75 ± 2.18	_	-3.96	0.00
Functional		13.33 ± 16.65	20.35 ± 10.02	24 ± 6.57	0.93	0.63	12.29 ± 11.31	14.5 ± 5.97	-	-1.16	0.24
Physical		8 ± 8.71	17.88 ± 9.79	26.33 ± 7.2	7.1	0.03	4.38 ± 7.34	11 ± 8.59	-	-2.39	0.02
Emotional		1.33 ± 2.3	11.41 ± 8.59	16.67 ± 8.54	7.04	0.03	1.54 ± 3.6	7.5 ± 5.85	_	-3.82	0.00
Total		22.67 ± 24.68	49.75 ± 22.3	67 ± 15.6	7.76	0.02	18.21 ± 14.56	33 ± 11.36	_	-3.01	0.00

P>0.05: Non-significant (NS), P< 0.05: Significant (S), P<0.01: Highly significant (HS)

Table 5 Severity of swallow, RSI, and A-DHI questionnaire scores before and after medical treatment among the participants

Subscale	e	Before medical treatment (mean ± SD)	After medical treatment (mean ± SD)	Wilcoxon test	P value
Severity	of swallow	4.48±0.79	2.58 ±0.94	-6.81	0.00
RSI		15.12±4.62	7.8±4.13	-6.7	0.00
A-DHI	Functional	20.37±10.1	12.73±10.46	-5.88	0.00
	Physical	18.23±10.01	5.7±7.99	-6.54	0.00
	Emotional	11.43±8.76	2.73±4.74	-5.59	0.00
	Total	50.03±23.03	21.17±15.12	-6.62	0.00

P>0.05: Non-significant (NS), P< 0.05: Significant (S), P<0.01: Highly significant (HS)

We attribute some of the success of the treatment protocol to criteria of patients' selection, who are more likely to benefit from PPI therapy and Prokinetics. Our sample of GERD patients was referred to the Phoniatrics clinic complaining of symptoms suggestive of laryngopharyngeal reflux (LPR) for at least two consecutive months (dysphonia, laryngospasm, vocal fatigue, excessive throat clearing, globus pharyngeus, chronic cough, postnasal drip, and dysphagia) and gave a positive history of most of the dietary risk factors, and their RSI is > 13. In a previous cohort study by Habermann et al. [32] who assessed the effectiveness of PPI therapy in patients with abnormal RSI and RFS, they measured treatment success by significant improvement in RSI and RFS scores, physician and patient assessments of the treatment effect, and quality of life measures. Their study defined RSI > 9 as abnormal, which is lower than the published threshold for this measure as we used in our study (RSI > 13).

In concordance with our methodology, Watson et al. investigated the agreement between the diagnosis of LPR using RSI, Reflux Finding score (RFS), and clinical examination without the use of RSI or RFS [33]. They found that the diagnosis of LPR by RFS did not agree with diagnosis by either RSI or clinical judgment. However, diagnosis of LPR showed by clinical consultation and RSI a fair agreement. The authors suggested that RSI and RFS are unreliable when used in isolation, but may be more useful when used in combination. Some authors conceived that treatment of LPR entails higher doses and longer time compared with GERD [22].

This study also explored the role of diet as a risk factor in LPR patients. As a whole, certain eating habits [23] are most responsible for the development or aggravating GERD that subsequently leads to the development of laryngopharyngeal reflux. The relationship between GERD and LPR is well known, but risk factors are unclear [25]. In the current study, analysis of data regarding dietary risk factors for reflux revealed that the most frequently reported factors were consuming the following products: fried food, fat, spicy food, sour foods, one big meal in the evening, citrus fruits, sweet, drinking tea, and meat. Surprisingly, the least frequently reported factors were smoking and drinking fruit juices. No subjects consumed alcohol as reported. Previous products may cause or aggravate GERD symptoms by various mechanisms, e.g., decreasing tension of the LES, delaying stomach evacuation, stimulating sensory receptors in the esophagus, or increasing gastric juice secretion [34, 35]. There have been conflicting reports about the association of smoking and alcohol consumption to LPR. Some studies suggested that both are related to LPR [36], while others refute this claim [37]. Thus, the hypothesis that the influence of various dietary factors is related to the presence of the disease symptoms needs to be verified in future ad hoc investigations.

Limitations in our study should be considered: (1) small sample size. (2) Our major limitation was to some extent the short duration of follow-up.

Future studies should include a large number of patients, a more detailed investigation of the risk factors of reflux, other symptoms' assessment, and long-term follow-up after weaning of PPI therapy. Future research

Table 6 Correlation between overall severity of swallowing and RSI/A-DHI before and after treatment

Subscale		Before medical	treatment	After medical treatment		
		R	P value	R	P value	
RSI		0.625	0.000	0.578	0.000	
A-DHI	Functional	0.216	0.097	0.253	0.051	
	Physical	0.422	0.000	0.467	0.000	
	Emotional	0.324	0.012	0.491	0.000	
	Total	0.391	0.002	0.519	0.000	

P>0.05: Non-significant (NS), P< 0.05: Significant (S), P<0.01: Highly significant (HS)

should incorporate refractory cases and patients with comorbidities such as asthma.

Conclusion

The results of this study entail that different dietary factors are present in LPR patients. LPR has a negative effect on patients' self-perception of swallowing-related problems as measured by RSI and DHI. The use of combined therapy (PPI and prokinetics) protocol improves the self-perception of swallowing-related symptoms in LPR patients. Further studies are needed to clearly define the risk factors and to evaluate the response of the various treatment options on other related symptoms.

Abbreviations

LPR: Laryngopharyngeal reflux; GERD: Gastro-esophageal reflux disorder; PPIs: Proton pump inhibitors; RSI: Reflux Symptom Index; DHI: Dysphagia Handicap Index; CLE: Clinical laryngoscopic examination; RFS: Reflux Finding score

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None

Authors' contributions

NFM and SEB contributed by designing the analysis and interpreting the data. NFM contributed to writing the manuscript. AAAt and MSE contributed by data collection, providing the intervention, writing the paper, and interpreting the results. NFM and AAAb contributed to writing the manuscript and interpreting the data. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Review Board of Faculty of Medicine, Beni-Suef University, Egypt, Approval No: FMBSUREC/01092020/ Atta. Written informed consent was obtained from all individual participants included in the study.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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