

Validity and Reliability of the Indonesian Version of Reflux Symptoms Score (RSS) and Reflux Sign Assessment (RSA)

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ABSTRACT

Introduction: Laryngopharyngeal reflux (LPR) symptoms are unspecific and make it difficult for clinicians to make a diagnosis. Several types of questionnaires have been developed to diagnose LPR such as the reflux symptoms score (RSS) and reflux sign assessment (RSA) questionnaires. However, the use of these questionnaires in Indonesia is still experiencing obstacles because there is no Indonesian version that has been tested for validity and reliability. This study aims to evaluate the validity and reliability of the Indonesian versions of RSS and RSA.

Methods: This study was an observational analytic study with a cross-sectional design involving 40 patients with LPR during January-March 2023. Questionnaire validity was assessed using external and internal validity methods, while reliability was assessed using internal consistency and test-retest reliability.

Results: The Indonesian versions of the RSS and RSA had good internal consistency with Cronbach's α values of 0.734-0.831 and 0.743-0.809 respectively. Test-retest reliability for RSS and RSA was also good with r of 0.930 and 0.842 respectively with $p < 0.001$ for both questionnaires. The Indonesian versions of RSS and RSA also proved to have good validity with high correlations between RSS with reflux symptoms index (RSI) and RSA with reflux finding score (RFS) with $p < 0.001$ for both questionnaires).

Conclusion: The Indonesian versions of the RSS and RSA questionnaires were found to be valid and reliable for the assessment of symptoms and diagnosis of LPR.

Keywords: LPR; Reliability; RSA; RSS; Validity

INTRODUCTION

Laryngopharyngeal reflux (LPR) is a disease characterized by the backflow of gastric contents into the larynx and pharynx which then comes into contact with the upper aerodigestive tract^{1,2}. Laryngopharyngeal reflux is characterized by dysphonia, mild dysphagia, globus pharyngeus, chronic cough, throat itching, and excessive throat mucus production. The majority of patients are unaware of their LPR condition and only 35% of patients report heartburn symptoms³. Recent studies reported that 10% of patients who visit the ENT clinic have symptoms caused by LPR. Laryngopharyngeal reflux also contributes to the onset of hoarseness in up to 55% of patients with dysphonia. In patients with LPR, up to 100% will complain of hoarseness on presentation, despite the absence of other classic reflux-related symptoms⁴. The prevalence of LPR in different countries shows varying results. A UK study reported an LPR prevalence of 34.4%, while another US study reported an LPR prevalence of 9.7%^{5,6}. However, due to limited data and diagnostic methods, the prevalence in Indonesia is still

unknown. LPR diagnosis is based on evidence of gastric acid reflux into the laryngopharynx. The gold standard examination to detect reflux is the multiple intraluminal impedance-pH (MII-pH) examination. Although this examination has been used as a gold standard, it has many shortcomings with a sensitivity of 50-80% and many patients cannot tolerate this examination. This test is also prone to showing false negative results with relatively expensive examination costs and limited availability^{7,8}.

Several types of questionnaires have been developed to diagnose LPR such as the reflux symptoms score (RSS) and reflux signs assessment (RSA) questionnaires. These questionnaires can also be used to follow changes in LPR symptoms during the treatment period^{8,9}. The RSS was first developed at the World ENT Congress in Paris, in 2016. The RSS content consisting of symptoms, structure, and presentation has been compiled based on expert opinion and systematic reviews that describe the symptoms of LPR based on current literature^{9,10}. Meanwhile, the RSA was also developed in Paris, in 2018. The RSA content consists of an assessment of the oral cavity, pharyngeal cavity, and larynx. The use of these questionnaires is due to the lack of specificity of LPR symptoms and the limitations of supporting examinations that can be performed in clinical practice¹¹. However, the use of these questionnaires in Indonesia is still experiencing obstacles because there is no Indonesian version that has been tested for validity and reliability. The purpose of this study is to evaluate the validity and reliability of the Indonesian version of the RSS and RSA.

METHOD

This study was an observational analytic study with a cross-sectional design to evaluate the validity and reliability of the Indonesian version of the RSS and RSA involving 40 subjects with LPR who were diagnosed based on Reflux Symptom Index (RSI) and Reflux Finding Score (RFS) questionnaire who came to the ENT outpatient clinic of Dr. Moewardi General Hospital, Surakarta, Indonesia during January-March 2023. Subjects with RSI values >13 and RFS >7 were diagnosed with LPR. Recruitment of research subjects used purposive sampling based on predetermined criteria. This study has been approved by the ethics commission of Dr. Moewardi General Hospital.

Reflux Symptom Score					
Dalam satu bulan terakhir, saya mengalami satu/beberapa gejala berikut ini					
Keparahan: 0= masalah tidak parah, 5 = masalah sangat mengganggu saat terjadi					
Frekuensi: 0= Saya tidak mengalami keluhan ini selama sebulan terakhir, 1,2,3,4 = Saya mengalami 1-2, 2-3, 3-4, 4-5 kali setiap minggu selama sebulan terakhir, 5= keluhan ini terjadi setiap hari					
	Frekuensi Gangguan	Keparahan Gangguan	Dampak Pada Kualitas Hidup		
			Skor Total		Skor Total
Gangguan Telinga, Hidung, dan Tenggorokan					
1. Suara serak atau masalah suara	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
2. Nyeri tenggorokan	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
3. Nyeri saat menelan	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
4. Sulit menelan (pil, cairan, atau makanan padat)	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
5. Mendehem	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
6. Rasa seperti ada yang menempel pada tenggorokan	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
7. Lendir berlebih di tenggorokan atau sensasi hidung berair	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
8. Tekanan/nyeri pada telinga (siang atau malam hari)	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
9. Lidah terasa seperti terbakar	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
10. Lainnya:	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
Gangguan Perut					
1. Sensasi panas pada perut, cairan asam lambung naik	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
2. Memuntahkan lagi cairan, makanan padat, atau bersendawa	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
3. Sakit perut	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
4. Diare	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
5. Sembelit	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
6. Gangguan pencernaan	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
7. Perut kembung dan/atau kentut-kentut	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
8. Bau mulut	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
9. Mual	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
10. Lainnya:	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
Gangguan dada/pernapasan					
1. Batuk setelah makan atau berbaring	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
2. Batuk (siang hari)	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
3. Sulit bernapas, sesak napas, atau mengi	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
4. Nyeri dada	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
5. Lainnya:	0-1-2-3-4-5	0-1-2-3-4-5	0-1-2-3-4-5
Menurut Anda apakah kuesioner ini baik dalam menilai keluhan Anda saat ini? YA- TIDAK Skor Total RSS: ... Skor Kualitas Hidup: ...					

Figure 1. The Indonesian version of reflux symptoms score

The inclusion criteria in this study were subjects aged >18 years old and not pregnant. Meanwhile, the exclusion criteria were smoking and alcohol, history of infection in the upper respiratory tract in the last month, illiterate, and having difficulty in communicating. Before signing the informed consent, subjects were given an explanation regarding the procedure and the aim of this study. Subjects were then asked to fill in personal data. Questionnaires were completed on days 0 and 7, respectively, since the subjects were enrolled in the study. Characteristics of the study subjects such as age, sex, duration of illness, education level, and comorbidities were also collected from each subject.

Reflux Sign Assessment		Skor	
Rongga mulut			
1. Eritema pilla anterior	tidak ada = 0	ada = 4	
2. Eritema uvula ± edema	tidak ada = 0	ada = 3	
3. Lidah berwarna putih	tidak ada = 0	ada = 2	
Subskor rongga mulut	.../9		
Rongga faring			
1. Eritema dinding nasofaring ± granulasi inflamasi	tidak ada = 0	ada = 2	
2. Eritema dinding posterior oro- atau hipofaring	tidak ada = 0	ada = 4	
3. Granulasi inflamasi dinding posterior oro- atau hipofaring	tidak ada = 0	ada = 3	
4. Hipertrofi tonsil lingual	Tidak ada hipertrofi = 0 Valecula hanya terlihat saat lidah dijulurkan = 3 Valecula tidak terlihat apa pun kondisi lidah = 4		
5. Kontak antara epiglotis dan hipertrofi tonsil lingual	tidak ada = 0	ada = 3	
6. Lendir lengket di tenggorokan	tidak ada = 0	ada = 4	
Subskor faring	.../21		
Laring			
Edema subglotis ± eritema	tidak ada = 0	ada = 1	
Eritema pita ventrikular ± edema	tidak ada = 0	ada = 2	
Epiglotis kemerahan ± edema	tidak ada = 0	ada = 3	
Komisura posterior & retro-krikoid	Tidak ada = 0 Hanya aritenoid/intra-aritenoid = 4 Menyebar ke arah komisura posterior		
1. Eritema			
2. Jaringan granulasi inter-aritenoid	tidak ada = 0	ada = 2	
3. Hipertropi komisura posterior	tidak ada = 0	ada = 5	
4. Eritema retro-krikoid	tidak ada = 0	ada = 3	
5. Edema retro-krikoid (=kontak antara area retro-krikoid & dinding posterior hipofaring selama bernapas/pembukaan glotis)	tidak ada = 0	ada = 4	
Pita suara			
1. Lendir lengket di endolaring	tidak ada = 0	ada = 3	
2. Eritema pita suara	tidak ada = 0	ada = 1	
3. Edema dari tepi bebas atau pita suara	tidak ada = 0	ada = 1	
4. Lesi pita suara (2 poin per lesi): granuloma, nodul, polip, edema Reinke, ulkus, keratosis	...		
Subskor laring	.../42		
Total Skor RSA	.../72		

Figure 2. The Indonesian version of the reflux sign assessment

RSS and RSA Questionnaires

The RSS consists of 25 questions related to LPR symptoms such as ENT disorders (10 questions), abdominal disorders (10 questions), and respiratory disorders (5 questions). Frequency and severity have a range of 0-5 and to get the score, the value obtained from the frequency was multiplied by the value obtained from the severity. Then, the scores of each symptom will be accumulated to obtain an RSS total score with a score range of 0-750. The RSS questionnaire also consists of a Quality of Life (QoL) score. This score evaluated the same questions as the RSS score by looking at the extent to which the symptoms affect the subject's quality of life. The QoL score was obtained by summing the scores of each symptom to obtain a QoL total score with a range of 0-250.

The RSA consisted of 3 main components based on symptom localization: oral cavities, larynx, and pharynx. The total score was obtained by summing the scores of each component. The maximum score that can be obtained was 72. The RSS and RSA questionnaires have a similar meaning where the

higher the score obtained the more severe the symptoms. Prior to use, the RSS and RSA questionnaires were each translated into Indonesian by two certified translators. The translation method used was the forward-backward method (Figure 1 & Figure 2). The results of the RSS and RSA translations were then compared with the English versions of the RSS and RSA.

Statistical Analysis

Statistical analysis to test the validity and reliability of the Indonesian versions of RSS and RSA was conducted with the help of IBM SPSS version 26 (Chicago, USA). The reliability test was conducted by assessing internal consistency. Internal consistency was evaluated using Cronbach's α coefficient. Cronbach's α coefficient value >0.7 indicates good internal consistency and reliability. Test-retest reliability was assessed by comparing the results of both the RSS and RSA questionnaires on day 0 and day 7.

RESULT

Subject's Characteristics

A total of 40 LPR subjects met the predetermined inclusion and exclusion criteria. The mean age of the subjects in this study was 52 years old with male subjects dominating. The male-to-female ratio was found to be 1.2:1. The mean disease duration was found to be 31.5 months. Most of the subjects had middle and high school education levels. Subjects in this study were also dominated by subjects with comorbidities. The subject's characteristics are presented in Table 1.

Table 1. Subject's Characteristics

Parameter	N (%) or mean \pm SD
Age	52.34 \pm 16.65
Gender	
Male	22 (55%)
Female	18 (45%)
Duration of illness (months)	31.53 \pm 16.83
Education Levels	
No education	1 (2.5%)
Elementary school	1 (2.5%)
Middle school	19 (47.5%)
High school	15 (37.5%)
University	4 (10%)
Comorbidities	
With comorbidities	22 (55%)
Without comorbidities	18 (45%)

Reliability

A total of 40 subjects who met the criteria filled out the Indonesian version of the RSS and RSA questionnaires on day 0 and day 7, respectively. The results of the reliability test using Cronbach's α and test-retest are presented in Table 2. RSS and RSA each for all components have Cronbach's α values >0.7 . Test-retest reliability for all RSS and RSA components all have r_s values ≥ 0.70 and p value <0.05 . The results of the reliability test are presented in Table 2 and Table 3. This result shows that the Indonesian versions of RSS and RSA have good reliability.

Table 2. Cronbach's α value and test-retest reliability of the RSS questionnaire

Component	Cronbach's α	r_s	p value
ENT score	0.734	0.902	<0.001
Abdominal score	0.802	0.784	<0.001
Respiratory score	0.791	0.848	<0.001
RSS total score	0.831	0.930	<0.001
QoL total score	0.774	0.912	<0.001

QoL= quality of life; r_s = Spearman rank correlation coefficient; RSS = reflux symptoms score

Table 3. Cronbach's α value and test-retest reliability of the RSA questionnaire

Component	Cronbach's α	r_s	p value
Oral cavity score	0.778	0.792	<0.001
Pharyngeal cavity score	0.792	0.763	<0.001
Laryngeal score	0.743	0.812	<0.001
RSA total score	0.809	0.842	<0.001

r_s = spearman rank correlation coefficient; RSA = reflux sign assessment

Validity

Based on Spearman rank correlation analysis, RSS total score correlated with RSI ($r_s = 0.813$; p value <0.001) and RSA total score correlated with RFS ($r_s = 0.782$; p value <0.001). This indicates that the Indonesian versions of RSS and RSA have good external validity. For internal validity in all components of both RSS and RSA, p value <0.001 was obtained for all components indicating good internal validity. The result of the validity test is presented in Table 4 and Table 5.

Table 4. Correlation between each component of the RSS questionnaire

Component	Score	p value
ENT score	49.1 \pm 10.57	<0.001
Abdominal score	42.3 \pm 7.99	<0.001
Respiratory score	24.2 \pm 5.5	<0.001
RSS total score	115.6 \pm 14.6	<0.001
QoL total score	32. \pm 10.57	<0.001

Table 5. Correlation between each component of the RSA questionnaire

Component	Score	p value
Oral cavity score	6.97 \pm 2.96	<0.001
Pharyngeal cavity score	8.92 \pm 1.68	<0.001
Laryngeal score	11.54 \pm 6.72	<0.001
RSA total score	24.59 \pm 8.95	<0.001

DISCUSSION

The RSS RSA questionnaire was first developed in Paris, France with the original French version. The French versions of RSS and RSA have previously been translated into English and have undergone validity and reliability testing with favorable results^{10,11}. The Indonesian versions of RSS and RSA used in this study were translated from their English versions. Several questionnaires have been developed as diagnostic tools for LPR such as the RSI and RFS questionnaires, but these questionnaires have not specifically and completely assessed the symptoms suffered by LPR patients¹². The RSS questionnaire fully assesses LPR symptoms comprising three main components and one

component to assess patient quality of life. These three components are ENT symptoms, gastrointestinal symptoms, and respiratory symptoms. Meanwhile, the RSA questionnaire consists of three main components, symptoms in the oral cavities, pharyngeal cavities, and larynx¹³.

The subject's characteristics in this study were similar to those in the previous study that assessed the reliability and validity of the English versions of RSS and RSA. In the previous study, the average age of subjects was 48 years, meanwhile in this study was 52 years¹⁰. The subjects in this study were predominantly male, with an average disease duration of 31.5 months, middle school education level, and had comorbidities. The results of this study also showed that the Indonesian version of RSS and RSA had good reliability. This was shown based on internal consistency assessed by Cronbach's α . The Cronbach's α values for each component and the total score of the Indonesian versions of RSS and RSA all had values ≥ 0.7 . Test-retest reliability between scores on day 0 and day 7 showed $r_s \geq 0.7$ and p value < 0.05 . This means that the Indonesian version of the RSS and RSA questionnaire instruments have good reliability (Table 3 & Table 4). Validity was assessed based on external and internal validity methods. External validity showed $r_s \geq 0.7$ and p value < 0.05 for RSS and RSA. Meanwhile, internal validity showed a p < 0.05 for all components of both RSS and RSA questionnaires. This means that the validity of the Indonesian version of the RSS and RSA is good so that it can be used to assess symptoms or as a diagnostic tool for LPR (Table 5 & Table 6). The limitation of this study is that the subjects in the study were only taken from outpatient clinics. In addition, the subject's characteristics such as age, sex, disease duration, education level, and comorbidities were not assessed for correlation.

CONCLUSION

The Indonesian version of RSS and RSA are reliable and valid instruments to evaluate symptoms and diagnosis of LPR.

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CONFLICT OF INTEREST

The authors reported no competing interests.

REFERENCES

1. Lechien JR, Akst LM, Hamdan AL, Schindler A, Karkos PD, Barillari MR, et al. Evaluation and Management of Laryngopharyngeal Reflux Disease: State of the Art Review. *Otolaryngol Neck Surg.* 2019;160(5):762–82.
2. Taraszewska A. Risk factors for gastroesophageal reflux disease symptoms related to lifestyle and diet. *Rocz Panstw Zakl Hig.* 2021;72(1):21-28.
3. Krause AJ, Walsh EH, Weissbrod PA, Taft TH, Yadlapati R. An update on current treatment strategies for laryngopharyngeal reflux symptoms. *Ann N Y Acad Sci.* 2022;1510(1):5–17.
4. Campagnolo A, Priston J, Thoen R, Medeiros T, Assunção A. Laryngopharyngeal Reflux: Diagnosis, Treatment, and Latest Research. *Int Arch Otorhinolaryngol.* 2013;18(02):184–91.
5. Nowak K, Sharma S, Kini S. *Laryngopharyngeal Reflux (LPR)*. In: *The SAGES Manual of Foregut Surgery*. Cham: Springer International Publishing; 2019. p. 119–30.
6. Kamani T, Penney S, Mitra I, Pothula V. The prevalence of laryngopharyngeal reflux in the English population. *Eur Arch Oto-Rhino-Laryngology.* 2012;269(10):2219–25.
7. Lechien JR, Bobin F, Muls V, Mouawad F, Dequanter D, Horoi M, et al. The efficacy of a

- personalized treatment depends on the characteristics of reflux at multichannel intraluminal impedance-pH monitoring in patients with acid, non-acid, and mixed laryngopharyngeal reflux. *Clin Otolaryngol.* 2021;46(3):602–13.
8. Andriani Y, Akil MA, Gaffar M, Punagi AQ. Deteksi pepsin pada penderita refluks laringofaring yang didiagnosis berdasarkan reflux symptom index dan reflux finding score. *Oto Rhino Laryngol Indones.* 2011;41(2):121.
 9. Zhang M, Chia C, Stanley C, Phyland DJ, Paddle PM. Diagnostic Utility of Salivary Pepsin as Compared With 24-Hour Dual pH/Impedance Probe in Laryngopharyngeal Reflux. *Otolaryngol Neck Surg.* 2021;164(2):375–80.
 10. Lechien JR, Bobin F, Muls V, et al. Validity and reliability of the reflux symptom score. *Laryngoscope.* 2020;130(3):E98-E107.
 11. Lechien JR, Rodriguez Ruiz A, Dequanter D, Bobin F, Mouawad F, Muls V, et al. Validity and Reliability of the Reflux Sign Assessment. *Ann Otol Rhinol Laryngol.* 2020;129(4):313–25.
 12. Wan Y, Yan Y, Ma F, Wang L, Lu P, Maytag A, et al. LPR: How Different Diagnostic Tools Shape the Outcomes of Treatment. *J Voice.* 2014;28(3):362–8.
 13. Lechien JR, Huet K, Finck C, Khalife M, Fourneau AF, Delvaux V, et al. Validity and Reliability of a French Version of Reflux Symptom Index. *J Voice.* 2017 ;31(4):512.e1-512.e7.