

Applicability of RSI and RFS questionnaires in the Polish language version

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ABSTRACT:

RSI and RFS questionnaires are a basic and common method used for initial diagnosis of laryngopharyngeal reflux (LPR). However, they only measure symptoms which may or may not be concurrent with LPR. The severity of these symptoms is assessed either by the patients themselves (with the use of the Reflux Symptoms Index – RSI) or by the doctor specialising in the field (with the use of the Reflux Finding Score – RFS). Therefore, the findings of the questionnaire may to a large extent depend on the study population – its demographic and cultural characteristics; the extent to which the medical terms used in the questionnaires are understood; and on the linguistic aspects and translation choices. As for the Polish language versions of these questionnaires, there is no reliable analysis of their consistency and if they reach the assumed goal. The studies we have conducted on a group of 84 patients show that we encounter at least one of the above-mentioned problems. Therefore, to make the questionnaires reliable and useful for diagnosis, it is necessary to conduct a formal validation of their translation and to conduct studies on reference groups.

KEYWORDS:

LPR, laryngopharyngeal reflux, Reflux Symptoms Index, Reflux Finding Score

INTRODUCTION

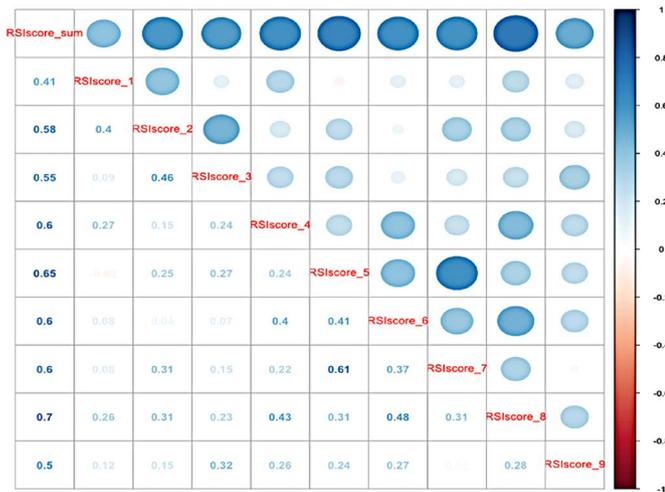
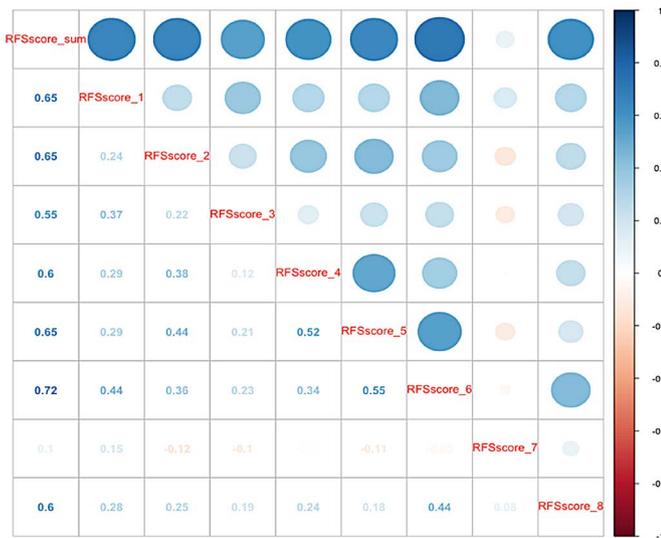
Laryngopharyngeal reflux (LPR) is a medical term introduced in 2002 by the American Academy of Otolaryngology-Head and Neck Surgery. It is a chronic pathological condition involving retrograde movement of liquid or gaseous gastric contents into the larynx and throat, resulting in acute or chronic symptoms of laryngeal mucositis. Damage to laryngeal structures is considered to be caused by pepsin rather than gastric acid. Consequences include laryngeal edema, squamous metaplasia of ciliated epithelium, and hypertrophy followed by the atrophy of mucous glands. The most common symptoms of laryngeal mucosal damage include hoarse voice, frequent throat clearing, foreign body sensation, chronic cough, secretion flowing down the posterior pharyngeal wall, and swallowing difficulties (dysphagia). The above symptoms are either caused by direct contact with the gastric contents or reflex-related. At the same time, no symptoms typical for gastroesophageal reflux disease (GERD) such as heartburn, burning stomach, or belching, are observed. About 10% of all ENT patients and more than 50% of patients with vocal disorders are considered to present with LPR symptoms. In order to facilitate the diagnostics of LPR, Belafsky had proposed two questionnaires aimed at measuring the incidence and intensity of symptoms suggestive of laryngopharyngeal reflux. The first questionnaire, Reflux Syndrome Index (RSI), is completed by the patient him-/herself while the other one, Reflux Finding Score (RFS), is completed by an otolaryngologist/phoniatician on the basis of laryngoscopic presentation. Using both questionnaires in control groups comprised of 25 and 40 groups, respectively, Belafsky had concluded that respective scores of more than 13 and 7 should be considered to be indicative of a preliminary diagnosis of LPR. This approach

was popularized in the literature and has been used ever since in ENT practice. However, serious doubts regarding the applicability of the questionnaires have been raised even with regard to the original, English version. In addition, it is questioned whether symptoms alone may be used for proper diagnostics. On the other hand, the usefulness of the surveys, e.g. when assessing the efficacy of treatment, is beyond doubt.

The main problem related to the RSI and RFS questionnaires is that they are dependent on subjective assessments of both responders, i.e. the patient (RSI) and diagnosing physician (RFS). Both questionnaires were developed in specific cultural and linguistic circumstances, in the context of a specific patient population, by researchers striving to achieve a specific goal. Consequently, all these aspects may lead to medical outcomes that may be rendered incomparable when original guidelines are translated in full.

For example, cultural perception of diseases and ailments within a society may have impact on the definition of a “serious problem”. What’s more, no translation can unambiguously match the original meaning of individual words. For example, the Polish term “chrząkanie” does not have to be understood in the same manner as “clearing one’s throat” by most Polish speakers. In addition, as LPR affects a specific population of patients, patient characteristics may differ between geographical regions for example due to sociodemographic reasons.

Numerous studies conducted in different countries seem to confirm the important impact of all these factors on the reliability of RSI and RFS questionnaires. Results obtained by Habermann and Printz confirm the diagnostic usefulness of the German and Gre-

Tab. III. Correlations between RSI questionnaire elements.**Tab. IV.** Correlations between RFS questionnaire elements.

ek translations. On the other hand, numerous practical difficulties were encountered for Korean and Persian translation. Translations into Italian and Arabic may be considered reliable; however, their final development was preceded by extensive analysis and a systematic translation and validation process.

For this reason, efficient practical use of the Polish language versions of RSI and RFS questionnaires requires their reliability being confirmed. This study presents the results of our analyses aimed at the investigation of the problem on the basis of the tests carried out in a group of our patients.

MATERIAL AND METHOD

The study population consisted of 83 patients at a mean age of 48.78 years (SD: 11.94), most of them female (80%), who had presented at the Department of Audiology and Phoniatics with throat and laryngeal complaints. The most commonly reported symptoms included hoarse voice, burning throat, sensation of foreign body

Tab. I. Results obtained for individual RSI questionnaire elements

	MEAN	SD	MEDIANA
RSI suma	23.28	7.15	24
RSI 1	3.23	1.26	3
RSI 2	3.60	1.37	4
RSI 3	3.29	1.42	3
RSI 4	1.82	1.25	2
RSI 5	2.17	1.50	2
RSI 6	1.87	1.21	2
RSI 7	2.23	1.45	2
RSI 8	2.88	1.48	3
RSI 9	2.22	1.38	2

Tab. II. Results obtained for individual RFS questionnaire elements

	MEAN	SD	MEDIANA
RFSI suma	8.13	3.39	8
RFSI 1	0.29	0.71	0
RFSI 2	1.42	0.96	2
RFSI 3	2.34	0.93	2
RFSI 4	1.01	0.55	1
RFSI 5	1.07	0.62	1
RFSI 6	1.41	0.70	1
RFSI 7	0.14	0.52	0
RFSI 8	0.43	0.83	0

Tab. V. RSI literature comparison. Values are Mean (SD). P-values of the t-test are listed in columns. NA: calculation was not possible. Significant differences are denoted by bolded font.

STUDY	RSI TOTAL	N	P.VALUE
Our data	23.28 (7.15)	84	NA
Habermann	13.8	1044	NA
Mesallam	20.2 (4.6)	40	0.014
Belfasky	20.9 (9.6)	25	0.181
Printza	19.86 (7.65)	53	0.009
Farahat	25.83 (8.28)	52	0.059
Vailati	18.0 (6.6)	22	0.002
Friedman	17.5 (11.47)	70	<0.001
Koufman	18 (11)	58	0.001
Reichel	23.1 (7.45)	30	0.907 [22]
Schindler	21.1 (6.6)	80	0.044
Musser	23.58 (9.1)	72	0.818
Mesallam	26.33 (9.78)	36	0.059
Mesallam	21.54 (9.38)	46	0.238
Domeracka	12.7 (7.97)	249	<0.001 [23]
Yadlapati	23.2 (7.3)	34	0.956

within the throat, secretion flowing down the posterior pharyngeal wall, and clearing one's throat. All patients were interviewed for the history of otolaryngological, phoniatic, and general disorders. Patients were asked to complete the Reflux Symptom Index

Tab. VI. RFS literature comparison. Values are Mean (SD). P-values of the t-test are listed in columns. NA: calculation was not possible. Significant differences are denoted by bolded font.

	RSI TOTAL	N	P.VALUE
our.data	8.14 (3.37)	84	NA
Habermann11	8.3	1044	NA
Mesallam07	9.3 (4.4)	40	0.108
Belfaskyo1	11.5 (5.2)	40	<0.001
Printza11	19.86 (7.65)	53	<0.001
Vailati12	7.7 (1.8)	22	0.557
Bilgen03	14.8 (1.9)	36	<0.001 [24]
Reichel08	14.9 (2.75)	30	<0.001
Schindler08	9.2 (2.7)	80	0.028
Musser09	10.97 (4.23)	72	<0.001
Mesallam13PhP	6.97 (2.00)	36	0.055
Mesallam13PhN	6.93 (1.99)	46	0.028
Domeracka13	11.57 (2.40)	249	<0.001
Yadlapati6	8.05 (2.55)	19	0.913

(RSI) questionnaire. Videolaryngostroboscopic assessment of the larynx was performed and followed by completion of the Reflux Finding Scale (RFS).

All statistical calculations were performed using the computational environment of the R software package. In a standard manner, P value of less than 0.05 was indicative of the null hypothesis being rejected. Normal distribution of data was assessed using the Cramer-von Mises test. Two-sample unequal variance Student's t-test was used to compare data with those of other studies where only means and standard deviations were reported. Appropriate implementation of the psych package of the R software was used to calculate Cronbach's.

RESULTS

The study population consisted of 83 patients at the mean age of 48.78 years (SD: 11.94), most of them female (80%). The mean RSI score was 23.28 (SD: 7.15) while the mean RFS score was 8.13 (SD: 3.39). Presented in tables are the parameters of response distribution for each element of the RSI questionnaire (Table 1) and the RFS questionnaire (Table 2). Distribution of total RSI scores may be considered close to normal (Cramer-von Mises test, $P=0.33$), in contrast to the distribution of total RFS scores which was inconsistent with that model (Cramer-von Mises test, $P=0.01$).

Notably, distributions of responses to the first three elements of the RSI questionnaire failed to cover the entire span of available answers; they are characterized by high mean and median values (≥ 3), since many highest-score responses were provided in contrast to a low number of lower-score or null-score responses. This indicates that these particular elements of the scale fail to properly differentiate between the study patients suggesting poor understanding of the question or inappropriate perception of the particular degree of disease severity.

In addition, the results obtained in a majority of patients exceeded the reference values defined by Belafsky, with 95% of subjects scoring more than 13 points in the RSI questionnaire and 53% of subjects scoring more than 7 in the RFS questionnaire. Particularly in the case of the RSI questionnaire, this percentage appears to be definitely too high compared to the estimate incidence of LPR in patients presenting with vocal problems.

When assessing cross-correlation between RFS and RSI questionnaires (Tables 3 and 4) only moderate correlations were observed between individual elements of both tools. For the RSI questionnaire, correlation of individual elements with the total score ranged from 0.41 (question 1) to 0.7 (question 8), while correlations between individual elements usually oscillated around 0.3.

For the RFS questionnaire, correlation of individual elements with the total score ranged from 0.1 (question 7) to 0.72 (question 6), while correlations between individual elements usually oscillated around about 0.3. RSI question 9 and RFS question 3 were the least correlated with the other elements of respective questionnaires. In addition, cross-correlation between RFS and RSI was very low. Only 3 elements of the RFS questionnaire (questions 1, 3, and 5) were found to be significantly correlated with the RSI questionnaire, albeit to a low degree of ca. 0.2. This effect was considerably low than that obtained in other studies pertaining to well-validated scales where most cross-correlations between RSI and RFS elements were significant and as high as 0.72. This might suggest that the Polish language versions of these questionnaires actually measure concepts and aspects different than those measured by validated questionnaires in other language versions.

DISCUSSION

RSI and RFS questionnaires are designed to measure the symptoms of LPR. Formal analysis of questionnaires' intrinsic consistency using Cronbach's assesses the degree in which individual questions are related to a single, integral construct. The values of Cronbach's range from 0 and 1 to indicate overall reliability of the verified assessment scale. The higher the value, the higher the probability that individual elements are related to the same cause. In the literature, it is commonly assumed that for a questionnaire to be considered acceptable for the measurement of a particular trait, Cronbach's should be greater than 0.7, with values greater than 0.8 being considered good. When Cronbach's is lower than 0.7, the questionnaire's assessment pertains to more than a single phenomenon.

In this study, Cronbach's for the RSI scale is quite low yet acceptable ($=0.75$). Importantly, the Polish language version of the RSI questionnaire appears to be markedly less consistent than other language versions such as Greek ($=0.865$) Italian ($=0.99$) and similarly to the Arabic version ($=0.72$). For the RFS questionnaire, Cronbach's is at the border of acceptability ($=0.7$).

All these results suggest that the currently binding Polish translations of both RSI and RFS questionnaires fail as measures of a single, consistent and common factor, contrary to their original purpose.

Importantly, it is unknown if, and to what degree, reference values and other applications of the RSI and RFS questionnaires as reported in international literature can be used in Polish conditions, i.e. whether the results obtained using the Polish versions in Polish patients are comparable to the results obtained elsewhere in the world. To this end, the results obtained in our study were compared to those obtained in most studies reported in the available literature. Comparisons for the RSI and RFS questionnaires are presented in Tables 5 and 6, respectively. In more than one half of the studies included in the analysis, significant differences were observed with regard to both RSI, and RFS questionnaire results. Notably, mean RFS values were usually lower than those obtained by other researchers. Moreover, with regard to individual questions of the RSI questionnaire the highest differences were observed with regard to questions 3 through 6.

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CONCLUSIONS

- Adaptation of RSI and RFS questionnaires in the Polish language version is required
- a randomized study is required to assess the LPR cut-off value of the RSI questionnaire in the Polish population.

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