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ORIGINAL PAPER

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An Instrument for Rating Quality of Life Related to Sore Throat in Patients Suffering from Acute Pharyngitis or Tonsillitis

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ABSTRACT

Introduction: Quality of life in patients with acute pharyngitis or tonsillitis is significantly lower than in healthy persons, and it should be taken into account when efficacy of new therapeutic options is investigated. **Objective**: The aim of this study was to develop and validate a reliable instrument that can measure quality of life in adult outpatients with sore throat caused by acute pharyngitis or acute tonsillitis. **Method**: The study was of a cross-sectional type, and assessed reliability and validity of newly developed questionnaire for measurement of quality of life in adult outpatients with sore throat (STQoL) caused by acute pharyngitis or acute tonsillitis. It was conducted on a sample of 282 patients, with mean age 39.0 ± 14.8 years, male/female ratio 104/178 (36.9%/63.1%). **Results**: Final version of the STQoL scale with 21 items showed excellent reliability, with Cronbach's alpha 0.949. It was temporally stable, and both divergent and convergent validity tests had good results. Factorial analysis revealed three domains, Social/psychic aspects, Physical aspects and Environmental aspects of sore throat related quality of life. **Conclusions**: The STQoL scale is reliable and valid specific instrument for measuring sore throat related quality of life, which is an important treatment outcome in patients with acute pharyngitis or tonsillitis.

Keywords: quality of life; sore throat; questionnaire; psychometric properties.

1. INTRODUCTION

Acute pharyngitis and tonsillitis are not life-threatening conditions, but may have profound negative influence on quality of life (1). Quality of life in patients with acute pharyngitis or tonsillitis is both statistically and clinically lower than in healthy persons, so available therapeutic options are aimed not only to eradicate causative agents and produce clinical cure, but to increase quality of life of the patients (2)

World Health Organization defines quality of life as "individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (3). It is essential that a physician has an insight into effects of the patients's disease on his or her quality of life, in order to make optimal choice of a therapeutic option and follow response of the treatment. There are numerous instruments for measuring general health-related quality of life (HRQoL), but specific questionnaire for assessing quality of life in patients with sore throat (ICD-10 diagnoses acute pharyngitis–J02 and acute tonsillitis–J03) is lacking. Earlier studies measured quality of life in patients with sore throat by general (generic) scale SF-36, while specific instruments were developed only for measuring quality of life after tonsillectomy of adenoidectomy (Tonsillectomy outcome inventory and Glasgow benefit inventory), than during sore throat in children (4), but not during acute pharyngitis and/or tonsillitis in adults (5- 7).

Acute pharyngitis and tonsillitis, if viral in origin, pass spontaneously for 5-6 days on average. Symptoms of sore throat abate in 51% of patients after 5 days, and in 91% after 7 days. Mean duration of sore throat symptoms is 4.7 days (8). Intensity of sore throat symptoms, and therewith decrease of quality of life, are the most

Item	Mean response	Standard deviation	Skewness	Kurtosis
How much your throat hurts, i.e. "burns" or "scratches"?	2.78	0.86	0.408	0.355
Does sore throat make swallowing difficult?	3.12	0.93	0.131	-0.605
How much sore throat affects your sleep?	3.48	1.04	-0.131	-0.876
Does sore throat makes breathing difficult?	3.79	0,93	-0.176	-0,974
Do you feel exhausted due to sore throat?	3.26	1.03	-0.198	-0.692
Are you able to take care about yourself completely?	4.34	0.89	-1.214	0.675
Do you walk less due to the sore throat?	4.05	0.97	-0.766	-0.229
How much sore throat affects your concentration?	3.67	0.96	-0.458	-0.326
Does sore throat make you depressive?	4.31	0.86	-1.146	0.720
Does sore throat interfere with your daily religious activities?	4.52	0.82	-1.823	2.854
Does sore throat affect your relations with family members?	4.14	0.93	-0.976	0.383
Does sore throat interfere with your work?	3.71	0.99	-0.572	-0.245
Does sore throat make following media more diffficult?	4.31	0.92	-1.504	2.293
Does sore throat interfere with your friendships?	3.82	1.01	-0.824	0.174
Does sore throat interfere with your sexual activities?	4.11	1.07	-1.078	0.370
Does sore throat make your colleagues at work uncomfortable?	4.08	0.99	-0.958	0.336
Do you have financial losses due to the sore throat?	4.20	0.90	-0.918	-0.057
Does sore throat impair your personal security?	4.62	0.69	-1.739	2.176
Does your sore throat prevent others to socialize with you?	4.27	0.88	-1.180	1.077
Does sore throat impairs your ability to withstand pollution of air in the city?	3.32	1.07	-0.213	-0.901
Does sore throat impairs your ability to withstand heat or coldness?	3.42	1.06	-0.322	-0.755

Table 1. Mean values, standard deviation, skewness and kurtosis of responses to items of Sore Throat Quality of Life (STQoL) scale (the responses are rated from 1 to 5 on a Likert scale).

pronounced during the first two days of illness; therefore, instruments for measuring quality of life should be administered within this time window, in order to catch maximal negative effect of the disease.

The aim of this study was to develop and validate a reliable instrument that can measure quality of life in adult outpatients with sore throat caused by acute pharyngitis or acute tonsillitis.

2. MATERIALS AND METHODS

Design

The study was of a cross-sectional type, and assessed reliability and validity of newly developed questionnaire for measurement of quality of life in adult outpatients with sore throat (STQoL) caused by acute pharyngitis or acute tonsillitis.

Construction of the new questionnaire

Development of the new questionnaire was undertaken according to the guidelines set by Robert F. DeVellis (9), through eight steps. In *the first step* (determining object of measurement) quality of life in adult outpatients with sore caused by acute pharyngitis or acute tonsillitis was chosen as an object of measurement, being important outcome of treatment. *The second step*, generating an item pool, was conducted through two brainstorming sessions with the authors, one week apart. It was taken care that certain number of items belong to each of the four aspects of quality of life: physical, psychical, social and environmental. In *the third step* (determining format for measurement) each item was constructed in the form of positive statement which should reflect certain element of quality of life. Five possible answers were offered for each statement, in the form of Likert's scale: "not at all", "a little", "medium", "a lot", and "extremely". The answers were rated from 5 ("not at all") to 1 ("extremely"). *The fourth step* (revision and correction of the initial pool of items) was made by the three members expert committee composed of an otorhinolaryngologist, an infectious diseases specialist and a clinical pharmacology specialist. Within *the fifth step* one validation item for discovering socially desirable behavior of respondents was included in the questionnaire: "I always try to communicate well with other people." In *the sixth step* the initial pool of STQoL's items was tested on 5 PhD students for clarity and comprehension. After the pilot a few minor changes were made, and then final Bosnian version of STQoL was copied and prepared for reliability testing on the sample of 282 outpatients (Annex 1). *The seventh* (evaluating the items) and *eighth* (optimizing the questionnaire length) steps are described below. A visual analogue scale for assessing quality of life related to sore throat was also offered to the study patients for validation purposes.

Supplementary questionnaires for validation purposes of the STQoL instrument

In order to make convergent criterion validation of the STQoL the study participants were offered short form (26 items) of generic instrument for measuring health-related quality of life WHOQoL BREF in Bosnian language (10). For divergent criterion validation purpose, the 10-item Emotional Regulation Questionnaire (ERQ) in Serbian language (minimally adapted for Bosnian language, see explanation of language issues in Bosnia and Herzegovina in the Discussion section) was used, which measures two strategies of emotional regulation: cognitive reappraisal and emotion suppression (11). Permissions to use these supplementary questionnaires were obtained before the start of the study from the Health Statistics and Health Information Systems division of the World Health Organization (for WHOQoL BREF) and from the first author of the publication about validation of the ERQ.

Data collection–population and the sample

Item	Factor 1 (Social and psychic aspects of quality of life)	Factor 2 (Physical aspects of quality of life)	Factor 3 (Environmental aspects of quality of life)
How much your throat hurts, i.e. "burns" or "scratches"?		0.861	
Does sore throat make swallowing difficult?		0.916	
How much sore throat affects your sleep?		0.847	
Does sore throat makes breathing difficult?		0.691	
Do you feel exhausted due to sore throat?		0.738	
Are you able to take care about yourself completely?	0.616		
Do you walk less due to the sore throat?	0.505		
How much sore throat affects your concentration?	0.456		
Does sore throat make you depressive?	0.685		
Does sore throat interfere with your daily religious activities?	0.588		
Does sore throat affect your relations with family members?	0.744		
Does sore throat interfere with your work?	0.670		
Does sore make following media more diffficult?	0.569		
Does sore throat interfere with your friendships?	0.768		
Does sore throat interfere with your sexual activities?	0.674		
Does sore throat make your colleagues at work uncomfortable?	0.740		
Do you have financial losses due to the sore throat?	0.618		
Does sore throat impair your personal security?	0.805		
Does your sore throat prevent others to socialize with you?	0.899		
Does sore throat impairs your ability to withstand pollution of air in the city?			0.826
Does sore throat impairs your ability to withstand heat or coldness?			0.728

Table 2. The rotated pattern matrix of the STQoL scale. An item belongs to the factor where its loading is listed. Insignificant loadings are not listed for the sake of clarity.

Final Bosnian versions of the both new (STQoL) and supplementary (WHOQoL BREF and ERQ) questionnaires were tested for reliability on outpatients who visited either general practitioners or specialists of infectious disease at state-owned outpatient health facilities in five cities of Bosnia and Herzegovina: Sarajevo, Tuzla, Zenica, Bijeljina and Zvornik. The visits took place from February to May, 2017. The inclusion criteria were ICD-10 diagnosis of either acute pharyngitis (J02) or acute tonsillitis (J03), established by managing physician, score ≥ 25 on Mini-Mental State Examination (MMSE), literacy, immunocompetence, without comorbidities and age between 18 and 65. The exclusion criteria were pregnancy, lactation, cognitive disorders, mood disorders, mental retardation, patients receiving immunosuppressants or cytotoxic drugs, HIV, splenectomy, diabetes mellitus, COPD, asthma, heart failure, allergic rhinitis and score < 25 on Mini-Mental State Examination (MMSE). The sample of the patients was of consecutive nature, i.e. all patients who visited their general practitioner or infectious diseases specialist on the survey day (and satisfied inclusion and exclusion criteria) were offered the questionnaires. During the first encounter the questionnaires were completed in two ways: at first, by the investigators who were questioning the patients, and second, by the patients themselves. The second encounter was two days later, and on that occasion both STQoL and supplementary scales were completed by the investigators who were questioning the patients, in order to test for temporal stability. The study was approved by the Ethics Committee of Clinical Center Kragujevac, Serbia. The patients were treated with due respect and care, according to the principles stated in Declaration of Helsinki.

Data analysis

Reliability testing

Reliability of the STQoL was tested by three methods. First, internal consistency was determined through calculation of Cronbach's alpha for the questionnaire as a whole. Second, the questionnaire was divided by split-half method to two parts with the same number of questions, and Cronbach's alpha for each of the parts was calculated. Using the alphas for both parts, number of questions in each part and average correlation between questions in both parts of the original questionnaire, the Spearman-Brown coefficient for the questionnaire as a whole was calculated by the Spearman-Brown "prediction" formula (12). Third, for each question mean score and their variances were calculated, in order to check their suitability for measurement of whole extent of sore throat related quality of life.

Factorial analysis

Exploratory factorial analysis of the questionnaire was made in order to discover principal factors (13). Principal axis factoring was used as extraction method (14), and it groups the items of a scale to a smaller number of factors which describe most of the variance of the responses to the scale items. Factors covering maximal variance are kept, while the others with small amount of variance are discarded. The amount of variance covered by each component is measured by its value. Suitability of the questionnaire and sample for factorial analysis was tested by Kaiser-Meyer-Olkin measure of sampling adequacy and by the Bartlett's test of sphericity. Then, the factors were extracted at first without rotation, with conditions that Eigenvalues had to be greater than 1.0, and using Scree-plot (the extracted factors were above the "elbow" of the graph). Second, oblique rotation of the referent axes was made, by the Promax method, and another extraction of

	STQoL score, rated by investigators	VAS scale	STQoL score, rated by patients	WHOQoL Bref, 1st item, rated by investigators	WHOQoL Bref, 2nd item, rated by investigators	WHOQoL Bref, Physical health, rated by investigators	WHOQoL Bref, Psychic health, rated by investigators	WHOQoL Bref, Social relations, rated by investigators	WHOQoL Bref, Environment, rated by investigators	WHOQoL Bref, 1st item, rated by patients	WHOQoL Bref, 2nd item, rated by patients	WHOQoL Bref, Physical health, rated by patients	WHOQoL Bref, Psychic health, rated by patients	WHOQoL Bref, Social relations, rated by ptients	WHOQoL Bref, Environment, rated by patients	ERQ score, rated by investigators	ERQ score, rated by patients
STQoL score, rated by investigators	1.000	.571**	.903**	.484**	.454**	.633**	.569**	.409**	.418**	.538**	.517**	.597**	.507**	.353**	.399**	.036	-.019
VAS scale	.571**	1.000	.514**	.445**	.387**	.508**	.441**	.365**	.322**	.432**	.419**	.495**	.403**	.333**	.334**	.078	.057
STQoL score, rated by patients	.903**	.514**	1.000	.445**	.387**	.595**	.480**	.376**	.379**	.582**	.518**	.644**	.570**	.400**	.471**	.066	.074
WHOQoL Bref, 1st item, rated by investigators	.484**	.445**	.445**	1.000	.701**	.598**	.638**	.492**	.502**	.824**	.637**	.541**	.563**	.464**	.467**	.120*	.116
WHOQoL Bref, 2nd item, rated by investigators	.454**	.387**	.387**	.701**	1.000	.631**	.618**	.446**	.421**	.624**	.849**	.597**	.594**	.437**	.434**	.152*	.132*
WHOQoL Bref, Physical health, rated by investigators	.633**	.508**	.595**	.598**	.631**	1.000	.754**	.574**	.552**	.636**	.632**	.884**	.726**	.548**	.551**	.137*	.154*
WHOQoL Bref, Psychic health, rated by investigators	.569**	.441**	.480**	.638**	.618**	.754**	1.000	.630**	.588**	.620**	.594**	.700**	.875**	.571**	.559**	.115	.111
WHOQoL Bref, Social relations, rated by investigators	.409**	.365**	.376**	.492**	.446**	.574**	.630**	1.000	.537**	.526**	.480**	.513**	.620**	.837**	.529**	.106	.125*
WHOQoL Bref, Environment, rated by investigators	.418**	.322**	.379**	.502**	.421**	.552**	.588**	.537**	1.000	.480**	.426**	.465**	.557**	.490**	.862**	.079	.068
WHOQoL Bref, 1st item, rated by patients	.538**	.432**	.582**	.824**	.624**	.636**	.620**	.526**	.480**	1.000	.714**	.644**	.664**	.531**	.539**	.143*	.157*
WHOQoL Bref, 2nd item, rated by patients	.517**	.419**	.518**	.637**	.849**	.632**	.594**	.480**	.426**	.714**	1.000	.676**	.642**	.501**	.497**	.169**	.171**
WHOQoL Bref, Physical health, rated by patients	.597**	.495**	.644**	.541**	.597**	.884**	.700**	.513**	.465**	.644**	.676**	1.000	.763**	.583**	.549**	.142*	.171**
WHOQoL Bref, Psychic health, rated by patients	.507**	.403**	.570**	.563**	.594**	.726**	.875**	.620**	.557**	.664**	.642**	.763**	1.000	.658**	.636**	.150*	.180**
WHOQoL Bref, Social relations, rated by patients	.353**	.333**	.400**	.464**	.437**	.548**	.571**	.837**	.490**	.531**	.501**	.583**	.658**	1.000	.579**	.137*	.179**
WHOQoL Bref, Environment, rated by patients	.399**	.334**	.471**	.467**	.434**	.551**	.559**	.529**	.862**	.539**	.497**	.549**	.636**	.579**	1.000	.060	.108
ERQ score, rated by investigators	.036	.078	.066	.120*	.152*	.137*	.115	.106	.079	.143*	.169**	.142*	.150*	.137*	.060	1.000	.885**
ERQ score, rated by patients	-.019	.057	.074	.116	.132*	.154*	.111	.125*	.068	.157*	.171**	.171**	.180**	.179**	.108	.885**	1.000

Table 3. Multi-trait, multi-method correlation matrix (non-parametric Spearman's coefficients). **. Correlation is significant at the 0.01 level (2-tailed), *. Correlation is significant at the 0.05 level (2-tailed)

the factors was made, using the same criteria as for the unrotated solution. The following was reported for the extracted factors: loadings, eigenvalues, and percentage of variance explained. The extracted factors were than named accordingly. All calculations were performed by SPSS statistical software, version 18.0.

Validity

Content validity of the questionnaire was evaluated by an independent panel of three experienced clinicians at Clinical Center Kragujevac, Serbia: an otorhinolaryngologist, an infectious diseases specialist and a clinical pharmacology specialist.

The criterion validity was tested by three methods: (1) comparison of the STQoL score with the Visual Analogue Scale (VAS) value, (2) convergent validity testing by comparison of the STQoL score with the WHOQoL BREF domains, 1st and 2nd item scores, and (3) divergent validity testing by comparison of the STQoL score with the score of the Emotional Regulation Questionnaire (ERQ). The correlations between scores on the questionnaires and/or VAS values were calculated. All calculations were performed by SPSS statistical software, version 18.0.

Temporal stability

Temporal stability of the STQoL results was tested by second completion of the questionnaires by the investigators who repeatedly interviewed the patients two days after the first encounter. The patients were scheduled for the second encounter at the end of the first one.

3. RESULTS

The first version of the STQoL questionnaire in Bosnian language contained 27 questions, which after the pilot and

minor adjustments was tested on the sample of 282 outpatients: mean age 39.0 ± 14.8 years, male/female ratio 104/178 (36.9%/63.1%), education: elementary school or less / high school / university = 15/164/103 (5.4%/58.1%/36.5%), living alone/in a family = 122/160 (42.5%/57.5%). The distribution of diagnoses within the study sample was as following: acute pharyngitis (n=199, 18.2%) and acute tonsillitis (n=83, 23%).

Reliability testing

After testing original 27 items from the questionnaire, and examining results of correlation matrix, mean values, variance, skewness and kurtosis of distributions of responses for each of the items, 6 items were removed, leaving final version of the STQoL questionnaire with 21 items. The removed items were with extreme means, extreme skewness and kurtosis, near zero variances and correlation coefficients with majority of other items below 0.3. Cronbach's alpha of the final version with 21 items was 0.949, when the scale was rated by the investigators. Mean values of responses, standard deviations, skewness and kurtosis for each item are shown in the Table 1. After division of the questionnaire by the split-half method the Spearman-Brown coefficient for the questionnaire as a whole was calculated by the Spearman-Brown "prediction" formula, and its value was 0.876. When the scale was rated by the patients themselves (at the first encounter), Cronbach's alpha was 0.952.

Factorial analysis

Factorial analysis was made by the principal axis factoring method. The Kaiser-Meyer-Olkin measure of sampling adequacy was 0.946 and the Bartlett's test of sphericity was significant (p = 0.000). Three factors were extracted after oblique rotation (Promax), explaining in total 60.23% of variance. The first factor bears 10.372 eigenvalues (49.39% of variance), the second 1.368 (6.52% of variance) and the third 0.907 eigenvalues (4.32% of variance). The rotated pattern matrix is shown in the Table 2. The items 6-19 belong to the first factor, which reflects social and psychic aspects of quality of life. The items 1-5 belong to the factor 2, which describes physical aspects of quality of life, and the remaining items 20 and 21 reflect environmental aspects of quality of life.

Validity

Construct validity of the questionnaire was confirmed by the panel of experts, who also helped with slight re-phrasing of the questions.

Divergent criterion validity was tested through non-parametric correlation between scores of the STQoL scale (when it was rated by investigator and by patients themselves) and scores of the ERQ scale (when it was rated by investigator and by patients themselves). Convergent criterion validity was tested through non-parametric correlation between scores of the STQoL scale (when it was rated by investigator and by patients themselves), scores of the domains, 1st and 2nd item of the WHOQoL BREF scale (when it was rated by investigator and by patients themselves) and VAS score. Non-parametric correlation was chosen due to non-normal distribution of majority of the scores. Spearman's correlation coefficients are shown in the Multi-trait, multi-method matrix (Table 3).

External validity was tested by non-parametric correlation between the STQoL scores as rated by investigators and patients, and estimate of severity of acute pharyngitis or tonsillitis made by a managing physician on a scale from 1 to 10. Both correlation between the STQoL score as rated by investigators and the physician's estimate, and correlation between the STQoL score as rated by patients themselves and the physician's estimate were significant (Spearman's rho -0.492, p=0.000 and -0.422, p=0.000, respectively).

Temporal stability

The STQoL scale showed satisfactory temporal stability: when rating (by the investigator) was repeated on the same patients two days later, the correlation between the scores (Spearman's coefficient) was 0.527 ($p < 0.001$). Cronbach's alpha after the repeated rating was 0.913.

4. DISCUSSION

Final version of the STQoL scale with 21 items showed excellent reliability, both when rated by the investigators, and by the patients themselves. It was temporally stable, and both divergent and convergent validity tests had good results, as well as external validation by physician-assessed severity of sore throat. Factorial analysis revealed three domains, Social and psychic aspects, Physical aspects and Environmental aspects of sore throat related quality of life.

Physical aspects are probably the main determinant of sore throat related quality of life, and are certainly the aspects which took the most attention of earlier studies. Pain was always taken into account (15, 7), and sometimes difficulties with swallowing (16), but quality of sleep and breathing were mostly missed. The items from Physical domain of STQoL cover both pain and difficulties with swallowing, sleep and breathing, giving wider picture how sore throat affects physical functioning of a patient. The responses on these items in our study had mean values close to mean of the range of possible answers, with acceptable variance, skewness and kurtosis (Table 1). Such results confirm their good discriminative ability to capture both mild, moderate and severe decrease in sore throat related quality of life (9).

Social and psychic aspects of sore throat related quality of life were taken into account in previous studies only if generic instruments for quality of life measurement were used, like SF-36, and the studies included mostly adults (1, 7). Majority of studies with sore throat related quality of life was performed on children, usually after tonsillectomy, and their social and psychic life were neglected (15, 17). The items of STQoL devoted to social and psychic aspects explore direct effect of sore throat on social activities and feelings of the patients. With exception of the work and friendships, all other items from this domain were rated by majority of patients as mildly affected by sore throat (mean answers were close to high-rated end of the Likert's scale (Table 1). However, underestimate of effects of sore throat on social aspects in our study may well be consequence of unhealthy lifestyle behaviors and non-adherence to physician's advice about taking rest and abstaining from social activities until the condition improves (18).

Sore throat has important influence on ability of patients with sore throat to withstand air pollution and environmental changes in temperature, as in our study the items from environmental domain were rated similar to items from physical domain. It is not surprising, considering traditional use of hot drinks and warm air to alleviate symptoms of sore throat (19), and also recent investigation which connected air pol-

lution with increased rate of sore throat (odds ratio 3.9) (20). Environmental items of the STQoL also showed excellent discriminative ability in our study.

It is also important to clarify language issues and titles used in our research. STQoL have been developed in Bosnian language, which is one of the official languages spoken in Bosnia and Herzegovina together with Croatian and Serbian (21). Standard Bosnian, Croatian, Montenegrin, and Serbian are different national variants and official registers of the pluricentric Serbo-Croatian language (22). Title of languages spoken in Bosnia and Herzegovina has been introduced after Bosnia and Herzegovina independence established in early 1990s, as the result of the disintegration of Yugoslavia where official language was Serbo-Croatian. In terms of practical everyday communication, there are no difficulties since the pre-war common standard language remains virtually unaltered (23). This is the reason why we could equally use Serbian translation for some questionnaires used in the study.

Main limitation of this study was inability to discriminate between viral and bacterial etiology of acute pharyngitis or tonsillitis, due to unavailability of rapid antigen tests. Bacterial throat infections have more severe symptoms than viral, so differences in quality of life estimates are expected. On the other hand, for validation of a scale purposes, it is beneficial to have participants with whole spectrum of a phenomenon which is measured (9). Future studies on subpopulations of sore throat patients (those with bacterial and those with viral etiology) are necessary to completely understand utility of the STQoL.

In conclusion, STQoL scale is reliable and valid instrument for measuring sore throat related quality of life which takes into account three aspects: social/psychic, physical and environmental. Identification of patients with low quality of life by this questionnaire should be a signal to change or amend therapy of sore throat in order to achieve cure faster and with less suffering.

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