

Validation of the St George's respiratory questionnaire Vietnamese Version in new pulmonary tuberculosis patients

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Research

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Abstract

Background: According to the Global Tuberculosis Report 2019, Vietnam is one of the 20 countries with the highest TB prevalence in the world. Pulmonary tuberculosis has a significant effect on lung functions, causing many obstacles in daily activities and affects the quality of patient's lives.

Methods: The case-series study conducted on 43 newly-diagnosed pulmonary tuberculosis patients at the Department of Tuberculosis - Military Hospital 103 within 4 months. The aims of the current study were to evaluate the validity of the Vietnamese version of the St. George's Respiratory Questionnaire and to investigate the relationship between SGRQ scores and the clinical and subclinical symptoms in new pulmonary tuberculosis patients.

Results: The results indicate that Vietnamese version of the SGRQ has high reliability with Cronbach's alpha of Total score was 0.9451, Cronbach's alpha of all domains was above 0.6, of which the Symptom domain was 0.6635, the Impact domain was 0.9069, the Activity domain was 0.9121. The study also showed that SGRQ score was proportional to the aggregate size of all cavities on chest X-ray ($r = 0.3772$) and inversely proportional to BMI ($r = -0.2843$), MGIT days to positivity ($r = -0.1635$).

Conclusions: The Vietnamese version of the SGRQ is a highly reliable and valuable questionnaire in assessing symptoms and life effects in new PTB patients. We recommend it as symptom measurement and quality of life evaluation in patients with new PTB in future studies.

Trial registration: The study protocol was approved by the Ethical Review Board Committee of Vietnam Military Medical University (IRB No. 250/2020/QĐ-HVQY) and by the local ethics committee of Military hospital 103. All participants had provided written informed consents for this study.

Background

Tuberculosis in general and pulmonary tuberculosis, in particular, remains the leading cause of disease burden worldwide. According to the Global Tuberculosis Report 2019, an estimated 10.0 million people fell ill with TB and approximately 1.3 million TB deaths in 2018 [1]. Almost all PTB patients experience lung function impairment which leads to limited mobility and decreased quality of their life [2, 3].

St. George's Respiratory Questionnaire (SGRQ) is a detailed questionnaire developed to measure health status in patients with lung diseases. It is mainly used to evaluate patients with COPD, asthma, and bronchiectasis and has been translated into many languages around the world [4–7]. Many studies are using SGRQ to evaluate and prognosis patients with latent tuberculosis and post pulmonary tuberculosis worldwide [8–10]. In Vietnam, the Vietnamese version of the SGRQ was created to be used as a measure of quality of life in patients with COPD, asthma and bronchiectasis.

However, the use of SGRQ in new pulmonary tuberculosis patients has not been studied much throughout the world. Besides, at present, there is no single scale to assess symptoms and impact of life in new PTB

patients. In this paper, the authors offer to evaluate SGRQ value in new PTB patients and examine the relationship between the SGRQ and clinical and subclinical symptoms in new PTB patients. We believe that the findings presented in our paper will provide significant evidence of the validity of the SGRQ as a reliable scale for pulmonary tuberculosis patients. In doing so, we hope that our research contributes to the global fight against tuberculosis.

Methods

The aims of the current study:

The purposes of the current study were to determine the validity of the Vietnamese version of the St. George's Respiratory Questionnaire and to evaluate the association between SGRQ scores and the clinical and subclinical symptoms in new pulmonary tuberculosis patients.

Study design:

This was a case-series study

Study participants:

All patients diagnosed with new PTB, over 18 years old were recruited into this study. The main inclusion criteria were: abnormalities on CXR compatible with PTB and a positive result on the MGIT culture (sputum or BAL); principal exclusion criteria were previous treatment for active TB disease.

Study location and time:

The current study was conducted at the Department of Tuberculosis - Military Hospital 103 from February 2020 to June 2020.

Sample size and sampling:

43 eligible patients with new pulmonary tuberculosis were included in the study.

Measurements

The dependent variable was the SGRQ score. The SGRQ is a self-assessment scoreboard exclusively for respiratory disease including 3 sub-sections: symptom section (including 8 questions), activity section (including 16 questions) and impact section (including 26 questions). Translations of the SGRQ questionnaire are available from the St George's library. To verify the translated version, a native Vietnamese speaker with a good English proficiency was selected and transitionally translated from the SGRQ English version into Vietnamese. The translated version has been critically reviewed to confirm equivalence in semantics, idioms, experiences, and concepts.

The independent variables were BMI (kg/m^2), MGIT days to positivity (day), Aggregate size of all cavities on chest X-ray (cm). BMI was computed as $\text{weight (in kilogram)} / (\text{height in meter})^2$. BMI (body mass index) under the cut-off point of 18.5 kg/m^2 was considered underweight [11]. The aggregate size of all cavities was calculated by adding up the widest diameters of all ones. To measure the widest diameter of

each cavity present on CXR, we used the standard radio-opaque ruler visible on the film. We used the MGIT BACTEC 960 system to perform liquid cultures. Time to MGIT positivity was calculated by the number of days from sample inoculation to detection of MTB growth.

Data collection

Data collection tools: Eligible participants were asked to complete the Vietnamese version of the St George's respiratory questionnaires.

Data collectors: Studying doctors were responsible for data collection.

Data collection procedures: All new PTB patients were invited to the study. A consent form was given to the participants before administering the research. It took about 15 minutes for each participant to complete the questionnaire. Personal information (eg: name, phone number...) was anonymized before the analysis. We also collected age, gender, BMI, CXR results, sputum smear microscopy results, time to MGIT positivity (sputum or BAL) and random blood glucose.

Data quality assurance: The data quality was monitored by a researcher in the studying team.

Data analysis and statistical methods

SGRQ score was calculated using an algorithm designed by PW Jones, St George Medical University Hospital, London, UK, available online from <http://www.healthstatus.sgul.ac.uk/sgrq-app>. The score ranges from 0-100 points, the higher the score, the greater the corresponding respiratory disease.

Continuous variables data were presented as means \pm SD [standard deviation] and categorical data were presented as numbers and percentages. We assessed internal consistency reliability using Cronbach's α coefficient. As adapted from Taber, K.S (2018) [12], internal consistency reliability for each scale is considered as excellent if Cronbach's α is ≥ 0.9 , strong if Cronbach's α is ≥ 0.8 , acceptable if Cronbach's α is ≥ 0.7 and reasonable if Cronbach's α is ≥ 0.6 . Correlations between SGRQ score and other factors were determined using the Pearson correlation coefficient. The known-group validity was evaluated based on different diagnoses using the student's t-test. The significance level was set at a p-value < 0.05 . The analysis was performed using STATA version 14 (College Station, Texas 77845 USA).

Results

Participants' characteristics

The study included 43 new PTB patients from February 2020 to June 2020. The characteristics of the whole sample (N = 43) are presented as follows in Table 1.

Table 1
Baseline characteristics of the participants

	N or mean \pm SD	%
Gender (n = 43)	30	69.77%
- Male	13	30.23%
- Female		
Age, years (n = 43)	49.23 \pm 20.12	
- Mean \pm SD	20–90	
- Range		
BMI, kg/m² (n = 42)	19.49 \pm 3.09	40.47%
- Mean \pm SD	20.115	54.76%
- Median	17	4.76%
- BMI < 18.5	23	
- 18.5 \leq BMI < 25	2	
- BMI > 25		
Random blood glucose-RBG (mmol/l) (n = 43)	8.80 \pm 6.15	30.23%
- Mean \pm SD	6.27	
- Median	13	
- RBG > 7.8 mmol/l		
Sputum smear microscopy results (AFB report*) (n = 36)	15	41.67%
- Negative (0)	21	58.33%
- Positive	2	5.56%
- Scanty	5	13.89%
- 1+	6	16.67%
- 2+	8	22.22%
- 3+		

Data are reported as n (%) or mean \pm SD (standard deviation).

*AFB report (WHO-IUATLD): No AFB = 0; 1 – 9 AFB per 100 fields = Scanty (report number of AFB); 10–99 AFB per 100 fields = 1+; 1–10 AFB per field = 2+; More than 10 AFB per field = 3+.

RBG = Random blood glucose; BMI = Body Mass Index; MGIT = mycobacteria growth indicator tubes;

	N or mean \pm SD	%
Days to MGIT positivity (n = 43)	13.97 \pm 8.35	
- Mean \pm SD	3–37	
- Range		
Data are reported as n (%) or mean \pm SD (standard deviation).		
*AFB report (WHO-IUATLD): No AFB = 0; 1 – 9 AFB per 100 fields = Scanty (report number of AFB); 10–99 AFB per 100 fields = 1+; 1–10 AFB per field = 2+; More than 10 AFB per field = 3+.		
RBG = Random blood glucose; BMI = Body Mass Index; MGIT = mycobacteria growth indicator tubes;		

Table 1 shows that male patients were 30/43 (69.77%), female patients were 13/43 (30.23%), the mean \pm SD age was 49.23 \pm 20.12 years, the youngest was 20, the oldest was 90. The average BMI of the study was 19.49 \pm 3.09 kg/m². The prevalence of underweight PTB patients was 54.76%. The mean RBG of the study was 8.80 \pm 6.15 mmol /l and 16.67% PTB patients had an RBG > 7.8 mmol/l. The mean days to MGIT positivity in 43 patients with new PTB was 13.64 \pm 8.40 days.

SGRQ reliability checking

Table 2
Mean, Max, Min, SD, median and Internal Consistency of SGRQ

Domain	Mean	Max	Min	Sd	Median	Cronbach's α coefficient
Symptom	30.79	78.61	0	18.9	30.17	0.6635
Activity	31.82	100	0	27.38	29.49	0.9121
Impact	25.62	80.44	0	22.06	22.62	0.9069
Total	28.47	80.07	0	21.09	28.6	0.9451

Table 2 presents the average score of symptom domain was 30.79 \pm 18.9, activity domain was 31.82 \pm 27.38, impact domain was 25.62 \pm 22.06, and mean total SGRQ score was 28.47 \pm 21.09. Internal consistency reliability results show that the SGRQ scale in Vietnamese version is a highly reliable scale, with Cronbach's alpha score of the total score of 0.9451, Cronbach's alpha of all other domains were above 0.6, in which the symptom domain was 0.6937, the impact domain was 0.9069, the activity domain was 0.9121.

Comparison of group

Check the difference between women and men by T-test in the three domains of SGRQ (symptom, activity, impact), the results in Table 3 show all P-value > 0.05. Therefore, there is no significant difference between the sexes in the indicators of the SGRQ scale.

Table 3
Known group validity

Gender	N	Symptom Mean \pm SD	Activity Mean \pm SD	Impact Mean \pm SD	Total Mean \pm SD
Male	30	30.33 \pm 18.04	30.74 \pm 29.16	24.08 \pm 23.27	27.18 \pm 22.04
Female	13	31.85 \pm 21.66	34.31 \pm 23.67	29.17 \pm 19.37	31.44 \pm 19.21
P value		0.8130	0.7001	0.4933	0.5490

Relationships between SGRQ score and BMI and subclinical symptoms

Table 4
Results of correlation between SGRQ scores and BMI, the aggregate size of all cavities on CXR, MGIT days to positivity (r, sig)

	BMI	Aggregate size of all cavities on CXR	MGIT Days to Positivity
Symptom	-0.1979 0.2090	0.3580 0.0184	-0.2591 0.0933
Activity	-0.1328 0.4019	0.2753 0.0739	-0.0789 0.6152
Impact	-0.3701 0.0158	0.3826 0.0113	-0.1712 0.2723
Total	-0.2843 0.0680	0.3772 0.0126	-0.1635 0.2949

As shown in Table 4, SGRQ showed correlation with the BMI, aggregate size of all cavities on CXR, MGIT days to positivity. Accordingly, SGRQ score correlated inversely with BMI and MGIT days to positivity ($r < 0$).

As a result of Table 4, we found an inverse correlation between the SGRQ score entries from symptom domain ($r = -0.1979$), activity domain ($r = -0.1328$), impact domain ($r = -0.3701$) to total score ($r = -0.2843$) with BMI. SGRQ score was positively correlated with aggregate size of all cavities on CXR (all $r > 0$), in which symptom domain had $r = 0.3830$, activity domain had $r = 0.2895$, impact domain had $r = 0.3956$, the total score had $r = 0.3938$. The proportional relationship between the aggregate size of all cavities and the SGRQ scores was statistically significant in all categories: Symptom (sig = 0.0184), impact (sig = 0.0113) and total score (sig = 0.0126), except for the activity item with sig = 0.0739 > 0.05

The relationship between MGIT days to positivity and SGRQ score entries was inversely proportional with r in all domains < 0 , meaning that the longer MGIT time to positivity, the lower the SGRQ score, but the sig were > 0.05 , so it was not statistically significant.

Discussion

This study investigated the validity and reliability of the SGRQ Vietnamese version in 43 patients with new PTB. Also, the current study was to explore the relationship between SGRQ score and BMI and subclinical symptoms. As stated in the WHO report (2019), the TB incidence in men/women was 2/1, in our study on 43 new PTB patients, the rate was $30/13 \approx 2.3$, equivalent to the WHO report. Although the WHO Global Tuberculosis Report 2019 also shows that tuberculosis can be acquired at any age, the highest incidence is in adult men (> 15 years old). Our study data was consistent with the WHO report [1].

BMI less than 18.5 kg/m^2 is considered underweight [11]. Compared with the study of Berhanu Elfu Feleke et al. on 1681 patients with TB, underweight PTB patients accounted for 43.7% [13] of the total and the research in Indian by Rachel W. Kubiak et al on 919 active TB patients, the majority (61%) of TB patients were underweight [14]. These results provided an additional fact that high proportions of TB patients were malnourished.

As reported by Rachel W. Kubiak et al, the mean RBG among TB patients overall was $10.04 \pm 5.74 \text{ mmol/l}$ and 49% TB patients had a RBG $> 7.8 \text{ mmol/l}$, which are higher than our study [14]. This can be explained by the differences in the diets between the two countries.

In our study, sputum AFB smears had a sensitivity of 58.33% as compared with the result of 67.5% from the research of Philip Mathew et al. were analyzed at two university-affiliated on 267 sputum samples [15].

The mean days to MGIT positivity in 43 patients with new PTB was 13.64 ± 8.40 days. The meta-analysis of M. Cruciani et al, on 1381 tuberculosis strains of 14,745 sputum samples showed that the mean MGIT days to positivity (BACTEC 960) was 13.2 days [16], similar to the results of our research.

The results obtained by Adnan et al. on 61 patients with PTB in Indonesia suggested that the mean score of SGRQ in three categories respectively: symptom domain was 56.64 ± 22.42 , activity domain was 52.46 ± 26.02 and impact domain was 46.78 ± 19.54 [17], which are higher than our study.

In agreement with previous studies on the reliability of SGRQ scale, the study by Adnan et al on PTB patients in Indonesia showed that the Cronbach's Alpha scores of all subscales (symptom, activity and impact) were above 0.7 [17], the results were similar to that of Zeina Akiki's study in patients with COPD and asthma in Lebanon with Cronbach's alpha score of 0.80 [4]. Research by M. Ferrer conducted in Europe on COPD patients with Cronbach's alpha results of symptom domain was > 0.7 and impact, activity domains were > 0.9 [6]. The Cronbach's α coefficient for Japanese version in Mariko Morishita-

Katsu's study on COPD patients was reported as 0.933 [5], comparable to Anees Ur Rehman's study in Malaysia on COPD patients where the Cronbach alpha report for SGQR was 0.87 [7].

However, the data on SGRQ study results in new pulmonary tuberculosis patients worldwide is limited. In our study on new PTB patients, the SGRQ scale in Vietnamese version is a highly reliable scale, with Cronbach's alpha score of the total score of 0.9451, Cronbach's alpha of all other domains were above 0.6, in which the symptom domain was 0.6937, the impact domain was 0.9069, the activity domain was 0.9121. Therefore, SGRQ can be used to assess symptom levels and life effects in patients with pulmonary tuberculosis. Our results demonstrated that there is no gender difference in the SGRQ scale. However, in the study of Adnan et al. the symptom and impact domain did not differ in gender, except for the activity domain [17]. In our opinion, perhaps due to religious and cultural differences in the two countries, Vietnamese women are not limited to participating in social activities and equally as men.

To our knowledge, our study is the first to demonstrate an association between SGRQ score and BMI and subclinical symptoms in new PTB patients. We found that SGRQ score was proportional to the aggregate size of all cavities on chest X-ray ($r = 0.3772$) and inversely proportional to BMI ($r = -0.2843$), MGIT days to positivity ($r = -0.1635$). This means that the lower the BMI, the higher the SGRQ score (the more respiratory symptoms and life effects) and the longer MGIT time to positivity, the lower the SGRQ score. However, not all relationships were statistically significant. The results of the correlation with $\text{sig} > 0.05$ can be explained by our study on a small sample size of 43 PTB patients. Therefore, it is necessary to conduct a larger sample size research to evaluate the relationship between the SGRQ score with the clinical and subclinical indicators.

There were some limitations in the present study. Firstly, the number of PTB patients in this study was small ($n = 43$) and this might be a cause of the results that were not statistically significant. Secondly, we could not follow up the participants to assess the SGRQ score after TB treatment. Future studies are suggested to conduct in a larger sample and in multiple centers to confirm the findings.

Conclusion

The application of the SGRQ scale in Vietnamese version on 43 new PTB patients at the Department of Tuberculosis - Military Hospital 103 from February 2020 to June 2020 shows that the SGRQ scale is valuable and reliable. In addition, SGRQ scores have a close associate with BMI and other subclinical symptoms. Although SGRQ can be applied in clinical practice to evaluate symptoms and affect life in patients with PTB, it needs further adjustment to be completely understandable and more suitable to Vietnamese culture.

List Of Abbreviations

PTB-Pulmonary tuberculosis

SGRQ- St. George's Respiratory Questionnaire

CXR- Chest X-ray

TB- Tuberculosis

COPD- Chronic obstructive lung disease

MGIT- mycobacteria growth indicator tubes

BAL- Bronchoalveolar lavage

BMI- Body Mass Index

WHO- World health organization

RBG- Random blood glucose

AFB- Acid-fast bacilli

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Ethical Review Board Committee of Vietnam Military Medical University (IRB No. 250/2020/QĐ-HVQY) and by the local ethics committee of Military hospital 103. All participants had provided written informed consents for this study.

Consent for publication

Not applicable.

Availability of data and materials

Data is available on request from the corresponding author.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

KMX was the guarantor of integrity of the entire study. HNT, KMX take responsibility for the study concept and design. Data acquisition was performed by HNT, QD, CTN and TTN. Analysis and interpretation of

data was completed by HNT, KMX and CTN. HNT, KMX prepared a draft of the manuscript that was modified by CTN, TTN and QD. The final version was read and approved by all authors.

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