ORIGINAL ARTICLE

Development of a Kannada Version of the Newest Vital Sign Health Literacy Tool and Assessment of Health Literacy in Patients with Tuberculosis: A Cross-Sectional Study at a District Tuberculosis Treatment Centre

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Abstract:

Background: Ensuring that the patient comprehends and correctly implements the physician's/health care worker's instructions is crucial in the treatment of Tuberculosis (TB). Our study aimed to assess the Heath Literacy (HL) of patients with TB using the Newest Vital Sign (NVS) HL tool translated to Kannada language. *Aim and Objectives:* To develop a translated version of the NVS HL tool in the Kannada language and assess the HL of patients with TB. *Material and Methods:* Two professional translators translated the NVS-United Kingdom version to Kannada language independently. The content of the translated version was assessed by a team of six medical and non-medical personnel, followed by back-translation of the modified version. The translated NVS tool, which was modified to culturally adapt the contents to the Indian scenario, was pilot tested among 15 individuals from the general population to determine the internal validity of the questionnaire, which indicated good reliability (Cronbach's alpha 0.806). Further, a cross-sectional study was conducted at a TB center in Karnataka, India. The translated NVS was administered to 50 patients with drug-sensitive and drug-resistant TB each. The correlation between the HL scores and educational and socioeconomic status was determined. *Results:* The median HL score of the study participants was 1, and the median time to answer the questionnaire was 10 minutes. The percentage of patients with limited, intermediate, and adequate HL scores were 54%, 32%, and 14%, respectively. A moderate positive correlation was seen between the educational level and the NVS scores (r_s = 0.480, $P < 0.001$). *Conclusion:* A large number of patients with TB have limited HL. The HL status of an individual correlates with the level of education but not with gender or socioeconomic status. NVS-Kannada is a reliable tool to measure HL in the Kannada-speaking population.

Keywords: Health literacy, Tuberculosis, Newest vital sign, Educational status

Introduction:

Tuberculosis (TB) is a significant health burden worldwide. The minimum treatment duration for TB is six months [1]. In the case of Drug-resistant

Tuberculosis (DR-TB), complex drug regimens needs to be prescribed which on occasion need to be modified based on individual patient characteristics and adverse events, if any, during the course of the treatment [2]. Inadequate knowledge about the disease and lack of adequate counselling are associated with treatment default [3]. Considering these aspects, ensuring that the patient comprehends and correctly implements the physician's/healthcare workers instructions is crucial and determines the outcome of the treatment. Therefore, the assessment of health literacy of a patient is an important aspect in the initial evaluation of the patient. Health Literacy (HL) refers to "the personal characteristics and social resources needed for individuals and communities to access, understand, appraise, and use information and services to make decisions about health" [4]. Based on the extent of HL, patients can be supported to improve their capacities to manage medications, the possible adverse effects, and follow-up.

Several HL tools, many in the form of questionnaires, have been developed and validated. The Newest Vital Sign (NVS) [5] is one of the reliable and valid HL tools that captures functional health literacy and numeracy, i.e. 'sufficient skills in reading and writing to be able to function effectively in everyday situations' [6]. The tool was developed by Weiss *et al*. [5] (copyright Pfizer Inc.) and available originally in English and Spanish languages; it has been subsequently translated and adapted for use in other countries [7]. A systematic review has shown the tool to perform moderately well in identifying patients with limited literacy [8]. The NVS consists of a nutrition label of an ice cream container accompanied by six questions, which are to be read and answered by the participant; it requires approximately three minutes for administration, and hence, is suitable for quickly assessing the HL of a patient in a clinic/hospital environment [5]. It assesses not only the reading ability but also comprehension and numerical skills, which are important in understanding the usual instructions that are given to a patient with TB.

In a study done in the United States general population, only 12% of adults had proficient HL, according to the National Assessment of Adult Literacy [9]. Fourteen percent of the adults had below basic HL. Considering diverse socio-cultural-economic structure of India, adequate HL would be crucial to the implementation and success of health programs. The World Health Organization End-TB strategy aims to reduce TB deaths by 95% and the incidence of new cases by 90% between 2015 and 2035 [10]. As per the Global TB report 2017, the estimated incidence of new TB cases in India was approximately 2.8 million per year, accounting for about a quarter of the world's TB cases [11]. The treatment success rates in India for Drug-sensitive (DS)-TB in 2015 was 75% and Drug-resistant (DR)-TB was 46%; the target treatment success rate for the year 2025 is 92% and 75% for DS-TB and DR-TB, respectively [12]. Assessing and ensuring optimum HL in the target population would contribute significantly to achieving the treatment targets. However, an important limitation in using the currently available HL tool in India is the availability of these tools only in the English language. Hence, we aimed to develop the NVS tool in the Kannada language, the main regional language spoken in the state of Karnataka, India, and use this translated version to measure HL in patients with DS-TB and DR-TB.

Material and Methods:

This cross-sectional study was conducted at the TB center of Wenlock District Hospital, which is affiliated with Kasturba Medical College, Mangalore. The hospital serves the medical needs of the population of Dakshina Kannada district and adjoining areas of the states of Karnataka and Kerala. According to the Revised National Tuberculosis Control Programme (RNTCP) annual status report for the year 2017, the annual notification rate for India was 135 per lakh cases and 105 per lakh for Karnataka state. The notification rate for Dakshina Kannada district, which consists of a mixture of urban and rural population of 2.2 million, was 84 per lakh population, of which 2.24% were drug-resistant cases [12]. The study was initiated after obtaining approval from the Institutional Ethics Committee, Kasturba Medical College, Mangaluru (approval number IEC KMC MLR 07-18/144). The study was conducted in accordance with the Indian Council of Medical Research National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and the Declaration of Helsinki. Written informed consent was obtained from all the study participants before the start of the study procedures.

All consenting patients with TB who were to be initiated on, or were currently on, treatment at Wenlock District Hospital from August 2018 to April 2019 were invited to participate in the study. The inclusion criteria included a diagnosis of DS-TB or DR-TB as per the Programmatic Management of Drug-resistant TB (PMDT) 2017 guidelines [2]; $\geqslant$ 18 years of age; native language being Kannada, and able to read Kannada; and willing to provide informed consent. Patients with a diagnosis of coexisting psychiatric illness or with difficulty in reading due to uncorrected visual problems were excluded from the study. The following demographic and clinical information were collected: age, gender, education, occupation, monthly income, and type of TB. The educational status was classified in accordance with the Indian Standard Classification of Education, 2014 [13]. In addition, the educational qualification and occupation of the head of the family and the family income was recorded to determine the socio-economic status of the participants in accordance with the revised Kuppuswamy's socioeconomic status scale [14]. Briefly, each of the three components is assigned a score, and the composite score is used to assign the socioeconomic class as follows: <5, lower socioeconomic class; 5-10, upper lower; 11-15, lower middle; 16-25, upper middle; 26-29, upper socioeconomic class.

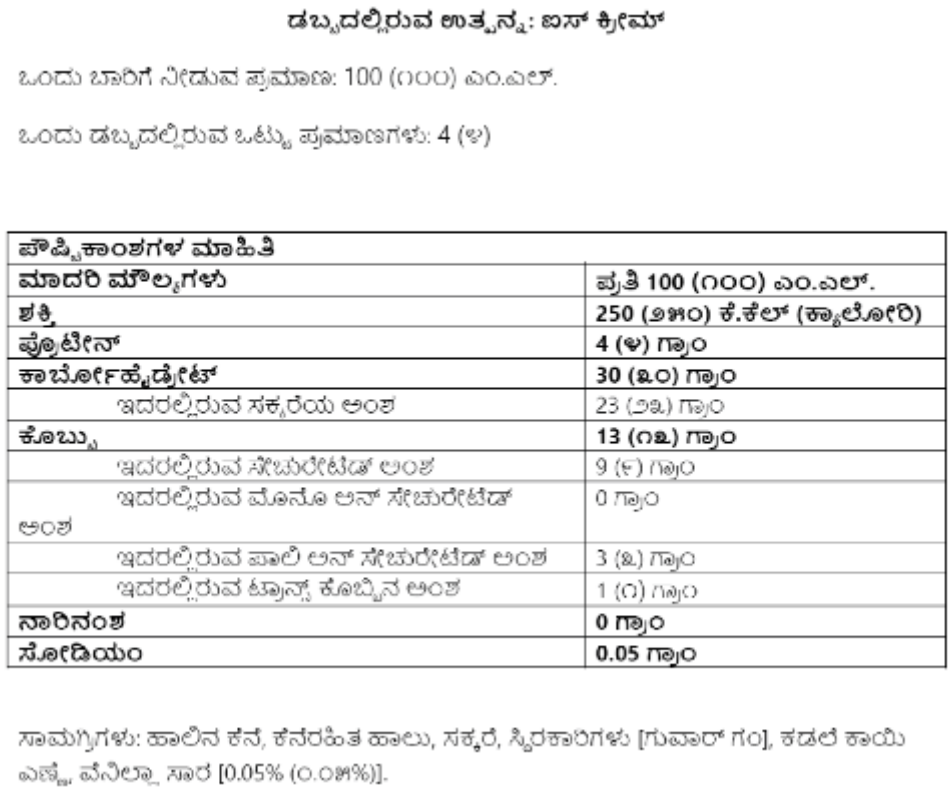
Translation and Validation of the NVS Tool:

We used the NVS-United Kingdom (UK) version [15], which is based, on the original NVS [5] but with modification and cultural adaptation to accommodate the labelling customs of UK. We used this version (permission obtained from authors of NVS-UK and original NVS as well as from the copyright holder Pfizer Inc.) since the labelling is similar to the nutritional food labels in India.

Two professional translators independently did the translation to the Kannada language. The study authors then finalized the provisional version of the tool; three medical faculty members, two from within the authors' institution and one from another in the city, who were proficient in both Kannada and English, reviewed this version. Two

individuals from the public, not related to the medical field, also reviewed the translated version and provided their opinion. Inputs from a nutritionist fluent in both Kannada and English was taken. Based on the opinions of these six individuals, a revised version was developed by the study authors, which was submitted to another professional translator for back-translation from Kannada to English. The following major modifications were included in the translated NVS: deletion of 'egg' as an ingredient since the ice creams available in India generally do not contain 'egg'; inclusion of numbers as Hindu-Arabic numerals as well as in Kannada script since the former is more commonly used for day-to-day transactions; retaining words such as 'protein' and 'carbohydrate' without translation to their corresponding Kannada words since most people are familiar with the English words due to their common usage; and since energy is expressed as kcal in the local food labels, '1050 kJ' present in the NVS-UK label was not included.

A pilot study was carried out using the revised translated tool among 15 consenting individuals from the general population to determine the feasibility and internal validity of the questionnaire. The Cronbach's alpha for the revised version was 0.806, which indicates good reliability; hence, the revised translated version (Fig. 1) was considered the final version to be used for the study.



ಡಬ್ಬದಲ್ಲಿರುವ ಉತ್ಪನ್ನ: ಐಸ್ ಕ್ರೀಮ್

ಒಂದು ಬಾರಿಗೆ ನೀಡುವ ಪ್ರಮಾಣ: 100 (೧೦೦) ಎಂ.ಎಲ್.

ಒಂದು ಡಬ್ಬದಲ್ಲಿರುವ ಒಟ್ಟು ಪ್ರಮಾಣಗಳು: 4 (೪)

ಪೌಷ್ಟಿಕಾಂಶಗಳ ಮಾಹಿತಿ	
ಮಾದರಿ ಮೌಲ್ಯಗಳು	**ಪ್ರತಿ 100 (೧೦೦) ಎಂ.ಎಲ್.**
ಶಕ್ತಿ	**250 (೨೫೦) ಕೆ.ಕೆಲ್ (ಕ್ಯಾಲೋರಿ)**
ಪ್ರೊಟೀನ್	**4 (೪) ಗ್ರಾಂ**
ಕಾರ್ಬೋಹೈಡ್ರೇಟ್	**30 (೩೦) ಗ್ರಾಂ**
ಇದರಲ್ಲಿರುವ ಸಕ್ಕರೆಯ ಅಂಶ	23 (೨೩) ಗ್ರಾಂ
ಕೊಬ್ಬು	**13 (೧೩) ಗ್ರಾಂ**
ಇದರಲ್ಲಿರುವ ಸೇಚುರೇಟೆಡ್ ಅಂಶ	9 (೯) ಗ್ರಾಂ
ಇದರಲ್ಲಿರುವ ಮೊನೊ ಅನ್ ಸೇಚುರೇಟೆಡ್ ಅಂಶ	0 ಗ್ರಾಂ
ಇದರಲ್ಲಿರುವ ಪಾಲಿ ಅನ್ ಸೇಚುರೇಟೆಡ್ ಅಂಶ	3 (೩) ಗ್ರಾಂ
ಇದರಲ್ಲಿರುವ ಟ್ರಾನ್ಸ್ ಕೊಬ್ಬಿನ ಅಂಶ	1 (೧) ಗ್ರಾಂ
ನಾರಿನಂಶ	**0 ಗ್ರಾಂ**
ಸೋಡಿಯಂ	**0.05 ಗ್ರಾಂ**

ಸಾಮಗ್ರಿಗಳು: ಹಾಲಿನ ಕೆನೆ, ಕೆನೆರಹಿತ ಹಾಲು, ಸಕ್ಕರೆ, ಸ್ಥಿರಕಾರಿಗಳು [ಗುವಾರ್ ಗಂ], ಕಡಲೆ ಕಾಯಿ ಎಣ್ಣೆ, ವೆನಿಲ್ಲಾ ಸಾರ [0.05% (೦.೦೫%)].

Fig. 1: Newest Vital Sign Health Literacy Tool – Kannada Version

During the administration of NVS, the participants were handed over the Kannada translated ice cream nutrition label, and the questions [15], which were also translated, were read aloud as many times as required. The participant was allowed to refer the label as often as desired. The six questions were asked in sequence with the maximum possible score being six. A score of 0−1 suggests a high likelihood of limited HL (limited HL); 2−3, the possibility of limited HL (intermediate HL); and 4−6, a sign of adequate HL (adequate HL) [5, 15].

Statistical Analysis:

The sample size was determined based on the findings of an earlier study using the Rapid Estimate of Adult Literacy in Medicine (REALM) HL tool in the general patient population in Karnataka, India [16]. The study showed that 75% of the patients had inadequate HL. With a sample size of 100, the confidence interval for the number of patients with low HL would be 65% to 83%. Hence, we enrolled 50 patients with DS-TB and 50 with DR-TB into the study. The sample size was calculated using the University of California San Francisco Online Sample Size Calculator.

The data analysis was performed using Statistical Package for Social Sciences version 11.5 (SPSS Inc., Chicago, IL, USA). The normality of data distribution was assessed using the Shapiro-Wilk test. The variables that were not normally distributed have been presented as median and Interquartile Ranges (IQR). Chi-square test was used to analyse non-parametric data. Mann-Whitney U test was used to compare two groups. Kruskal Wallis H test with Dunn's post hoc was used for multiple group comparisons. Spearman's rank-order correlation (r_s) was used to determine the association between the level of education and the HL scores. A *P*-value <0.05 was considered statistically significant.

Results:

Fifty patients with DS-TB and 50 with DR-TB participated in the study. Twenty-three percent of the participants were females. The mean age (standard deviation) of the study participants was 42.11 years (14.01). The demographic and clinical characteristics of the study participants are presented in Table 1. Significantly more number of DR-TB patients were in the lower socioeconomic class compared with DS-TB patients (upper lower, 56% versus 26%, respectively, p = 0.016).

The median (IQR) time taken by the participants to answer the questionnaire was 10 minutes (10–12). The median HL score of the study participants was 1(0–3). Questions 1, 2, 3, 4, 5, and 6 were answered correctly by 22%, 32%, 27%, 14%, 61%, and 16%, respectively. The percentage of patients with limited, intermediate, and adequate HL scores were 54%, 32%, and 14%, respectively. The time taken and HL scores in patients with DS-TB and DR-TB are shown in Table 2. There was no significant difference in the HL scores of patients with DS-TB and DR-TB. A moderate positive correlation was seen between the educational level and the NVS scores ($r_s = 0.480$, $p < 0.001$) (Fig. 2). Table 3 presents the HL score based on the level of education.

With regard to gender, a significantly higher percentage of women had education above 10th standard compared with men (60.9% versus 20.8%, $\chi^2 = 13.554$, $p < 0.001$). However, there was no statistically significant difference in the time taken to answer the questionnaire [median (IQR), 10 minutes (10-12) in both groups, p = 0.497] and the HL score (1 [0-3] in both groups, p = 0.940).

Table 3 also shows the HL scores of the study participants based on their socioeconomic status. Participants in the lower middle socioeconomic class had a significantly higher HL score compared with those in the upper lower class (p = 0.001). The educational status of the study participants and their socioeconomic class is shown in Table 4.

Table 1: Demographic and Clinical Characteristics of the Study Participants

Patient characteristics	DS-TB (N = 50)	DR-TB (N = 50)	*p*
Females, N (%)	8 (16)	15 (30)	0.096
Age in years, (Mean SD)	43.82 ± 15.77	40.40 ± 11.91	0.224
Level of education, N (%)			
Class 1-5	6 (12)	11 (22)	
Class 6-8	10 (20)	12 (24)	
Class 9-10	17 (34)	14 (28)	
Class 11-12	7 (14)	2 (4)	
Beyond 12th class	10 (20)	11 (22)	
Family income per month in Indian Rupees, median (IQR)	17000 (14000–25000)	10000 (6000–15000)	<0.001
Comorbidities,* N (%)			
Diabetes mellitus	11 (22)	11 (22)	
Hypertension	2 (4)	0	
HIV infection	2 (4)	3 (6)	
Socioeconomic class, N (%)			
Upper (N = 3)	3 (6)	0 (0)	0.016
Upper middle (N = 18)	12 (24)	6 (12)	
Lower middle (N = 37)	21 (42)	16 (32)	
Upper lower (N = 41)	13 (26)	28 (56)	
Lower (N = 1)	1 (2)	0 (0)	

**Not all comorbidities have been listed*

HIV, human immunodeficiency virus; DS-TB, drug-sensitive tuberculosis; DR-TB, drug-resistant tuberculosis; SD, standard deviation; IQR, interquartile range

Table 2: Newest Vital Sign Test Performance of Patients with Drug-sensitive and Drug-resistant Tuberculosis

	DS-TB N = 50	**DR-TB** N = 50	***P*-value**
Time to completion, median (IQR)	12 (10–15)	10 (10–10)	0.02
NVS score, median (IQR)	1 (1–3)	1 (0–3)	0.659
NVS HL category, N (%)			
Limited HL	26 (52)	28 (56)	
Intermediate HL	17 (34)	15 (30)	
Adequate HL	7 (14)	7 (14)	

DS-TB, drug-sensitive tuberculosis; DR-TB, drug-resistant tuberculosis; HL, health literacy; NVS, Newest Vital Sign; IQR, interquartile range

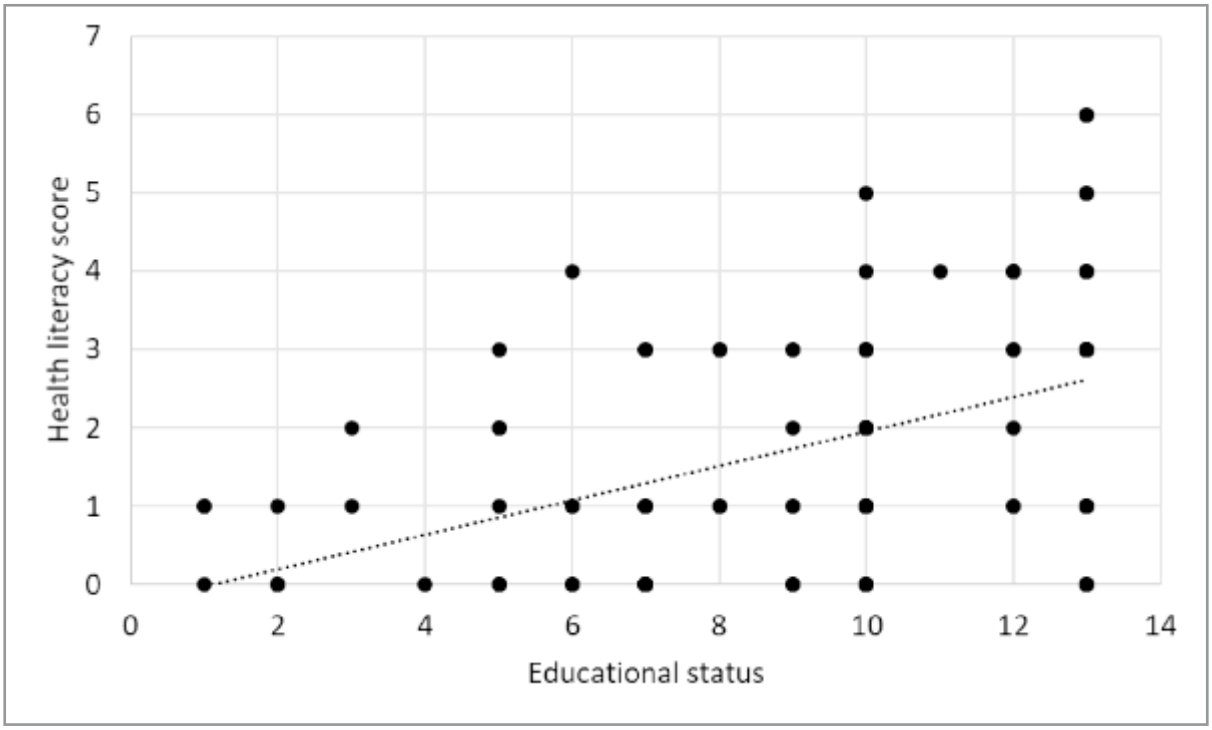


Fig. 2: Correlation between the Level of Education of Patients with Tuberculosis and their Health Literacy Scores. A Moderate Positive Correlation (Spearman's Rank-Order Correlation) Was Seen ($r_s = 0.480$, $P < 0.001$).

Table 3: Newest Vital Sign Health Literacy Scores of Patients with Tuberculosis Based on their Level of Education and Socioeconomic Status

Level of education	Health literacy, N (%)			*P*-value
	Limited (NVS score 0–1)	Intermediate (NVS score 2–3)	Adequate (NVS score 4–6)	
Class 1–5 (N = 17)	13 (76.5)	4 (23.5)	0	0.001
Class 6–8 (N = 22)	17 (77.3)	4 (18.2)	1 (4.5)	
Class 9–10 (N = 31)	15 (48.4)	14 (45.2)	2 (6.5)	
Class 11–12 (N = 9)	2 (22.2)	3 (33.3)	4 (44.4)	
Beyond 12th class (N = 21)	7 (33.3)	7 (33.3)	7 (33.3)	
Socioeconomic class				
Upper (N = 3)	0	1 (33.3)	2 (66.7)	0.001
Upper middle (N = 18)	9 (50.0)	8 (44.4)	1 (5.6)	
Lower middle (N = 37)	14 (37.8)	12 (32.4)	11 (29.7)	
Upper lower (N = 41)	30 (73.2)	11 (36.8)	0	
Lower (N = 1)	1 (100)	0	0	

NVS, Newest Vital Sign

Table 4: Educational and Socioeconomic Status of the Study Participants with Tuberculosis

Level of education	Socioeconomic class N (%)				
	Lower	Upper lower	Lower middle	Upper middle	Upper
Class 1–5 (N = 17)	1 (100)	16 (39)	0	0	0
Class 6–8 (N = 22)	0	15 (36.6)	3 (8.1)	4 (22.2)	0
Class 9–10 (N = 31)	0	10 (24.4)	14 (37.8)	7 (38.9)	0
Class 11–12 (N = 9)	0	0	8 (21.6)	1 (5.6)	0
Beyond 12th class (N = 21)	0	0	12 (32.4)	6 (33.3)	3 (100)

Discussion:

We translated the NVS-UK HL tool to Kannada language and used it to assess the HL levels in patients with TB. To the best of our knowledge, this is the first general HL tool in India to be available in the regional language. Gomez *et al.* [17]. evaluated English and Malayalam-translated Health Literacy in Dentistry HL questionnaire; Nair *et al*. [18] developed the Eastern-Middle Eastern-Adult-Health Literacy 13-point Questionnaire in English and translated it to Arabic, Hindi, Urdu, Tagalog, and Malayalam for evaluation of HL in patients in Eastern and Middle Eastern cultures. The former is specific to dentistry and involves questions on dental health aspects, and the latter involves questions requiring the participant to answer regarding his/her understanding of or ability to perform health-related tasks on a 5-point Likert scale. Unlike the general HL tools such as the NVS or REALM, the above-mentioned HL questionnaires do not measure reading, comprehension, or numeracy skills.

Among the 100 patients who completed the exercise, 54% had limited HL. Earlier studies conducted in the same geographical location in patients with diabetes mellitus and the general population using the English version of REALM showed that 63.12% and 33.5%, respectively, had low HL equivalent to sixth grade of education or less [16, 19]. The figures are not directly comparable, considering that the language of the tool used was different, and the participants are likely to differ in terms of their socioeconomic status. Moreover, REALM tests the ability of participants to pronounce a set of common medical words but not comprehension or numeracy skills [20-21]. The fact that the HL scores of our study participants largely corresponded with their educational level confirms that the translated tool did indeed measure what it was intended to. The finding with regard to the socioeconomic class also supports this; those in the lower middle class had better HL scores compared with those in the upper middle, with the latter group having lesser education compared with the former. However, studies have also shown that the education status does not always reflect the HL level in an individual [15-16]. This only further establishes the need to evaluate HL during a patient encounter.

An important purported advantage of the NVS over other HL tools is the short time required to complete the exercise, making it suitable for use in the clinics. In the study by Weiss *et al.* [5], a mean time of 2.9 minutes (SD 1.2 minutes; range = 1.5–6.2 minutes) was recorded based on the responses of 24 participants. The median (IQR) time recorded in our study was 10 minutes (10–12), which is significantly more than anticipated. One of the possible reasons for the longer time to completion is the lack of familiarity with analysing and interpreting food labels in our population [22]. All pre-packaged, locally manufactured, and packaged food, including ice creams, bear a nutrition label in accordance with the national regulations. So, while familiarity is not an issue, people often do not actively use the information to make proper food choices [22]. This is reflected in the opinions of the participants in our study; in fact, a common complaint was that one does not eat ice cream on an every-day basis, and hence, it is difficult to answer the questions. This situation is not unique to our study; in the study by Fransen *et al.* [23], who tested different HL tools translated to Dutch in the Dutch population, many patients expressed that they were not familiar with the type of food label

and had difficulties calculating in portions instead of grams. Hence, this aspect needs further study to determine the real-world usefulness of the tool. Also, its usefulness over REALM [20], requiring less than 3 minutes, and the shorter version of TOFLA, S-TOFLA [24], requiring 10 minutes, will need to be determined.

Knowledge regarding the disease and treatment contributes significantly to the treatment outcome. In a study among a tribal population in India with a high burden of TB, more than half of the studied sample had not heard of the disease [25]. The lack of knowledge coupled with an inability to understand the information provided in educational materials is a cause for concern. Use of HL tools will help in rapidly screening the individuals who require extra care and not just providing printed information or a set of instructions at the beginning of drug therapy [26]. A review of the available treatment literacy materials for patients undergoing treatment for TB showed that there were limited comprehensive patient-centered documents, highlighting the need for a consensus as to the essential elements of TB treatment literacy [27]. Locally identified and developed health literacy materials may help in achieving the desired results more completely [28]. The success of any disease control program relies on public participation; lack of adequate HL is an important deterrent. Limited HL is associated with reduced adoption of protective behaviours such as immunization and an inadequate understanding of medications [29]. In our study, although a larger percentage of female participants had more education compared with males, the NVS score as well as the time required to complete the exercise was similar; however, gender differences have been reported by some studies [30, 31]. The lack of difference in the NVS scores could be because of the relatively lesser number of female participants; the latter finding is in agreement with the observation that the burden of TB is about twice in males compared with females [32]. Nonetheless, our findings are similar to that reported by a review of 39 studies that assessed TB-related health literacy that found no significant gender-related differences in TB-related knowledge [33]. However, it is to be noted that none of these studies used a specific HL tool for assessment.

Our study has limitations. The validity of the tool could not be completely established, as no validated HL tool is available in the local language for comparison. The sample size was small and from a single geographic location, and hence, may not be representative of the entire TB population; however, the gender distribution, level of education, and the socioeconomic status were largely in agreement with a recent nationwide survey [34].

Conclusion:

Most of the patients with TB have limited HL; the HL scores correlate well with the educational status of the individual. Interventions to improve HL status in TB patients are required. In this context, the NVS-Kannada version is a reliable tool to measure HL; however, the usefulness of NVS in the clinical setting, with regard to patient acceptability and time for assessment, need to be further studied.

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