

Analysis of the Current Research Status of Patient-Reported Outcome Assessment Tools for Obstructive Sleep Apnea: A Postprint

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Abstract

Obstructive sleep apnea (OSA) is a common sleep-related breathing disorder that predisposes to or exacerbates various diseases, often resulting in varying degrees of decline in patients' quality of life. Patient-reported outcome (PRO) assessment instruments provide an effective means for evaluating quality of life and clinical efficacy. Existing OSA-PRO assessment instruments are numerous, predominantly developed abroad, primarily covering domains such as symptoms, daily activities, social activities, and psychological emotions, with item counts ranging from 1 to 84, predominantly employing Likert-type response scales, and their development and evaluation utilize Classical Test Theory. Future research should focus on evaluating the psychometric properties and methodological quality of OSA-PRO assessment instruments; developing, revising, and evaluating OSA-PRO assessment instruments by integrating Classical Test Theory and modern measurement theories; strengthening research on the minimal clinically important difference of OSA-PRO assessment instruments; and developing OSA-PRO assessment instruments that highlight the distinctive features of traditional Chinese medicine clinical efficacy.

Full Text

Research Status of Patient-Reported Outcome Measurements for Obstructive Sleep Apnea

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Abstract

Obstructive sleep apnea (OSA) is a common sleep-related respiratory disorder that can easily induce or aggravate various diseases, often causing varying degrees of decline in patients' quality of life. Patient-reported outcome (PRO) assessment tools provide effective means for evaluating both quality of life and clinical efficacy. Numerous OSA-PRO assessment tools are currently available, primarily developed in foreign countries, mainly covering domains such as symptoms, daily activities, social activities, and psychological emotions, with item counts ranging from 1 to 84. Likert scales are predominantly used as response formats, and their development and evaluation employ Classical Test Theory. Future research should focus on evaluating the psychometric properties and methodological quality of OSA-PRO assessment tools; combining Classical Test Theory with Modern Test Theory to develop, revise, and evaluate OSA-PRO tools; strengthening research on minimal clinically important differences for OSA-PRO tools; and developing OSA-PRO assessment tools that highlight the clinical efficacy characteristics of traditional Chinese medicine.

Keywords: Sleep apnea, obstructive; Patient-reported outcome; Respiratory tract diseases; Review

Introduction

Obstructive sleep apnea (OSA) is a common sleep-related breathing disorder characterized clinically by irregular snoring, apnea, arousal, nocturia, daytime sleepiness, and cognitive dysfunction [1-2]. In recent years, the prevalence of OSA has increased annually. Approximately one billion adults aged 30-69 worldwide suffer from OSA, with China having the highest number of affected individuals at 176 million [3]. As a systemic disease, OSA is prone to complicating or exacerbating cardiovascular, cerebrovascular, endocrine, and metabolic diseases across multiple systems and organs, while also causing anxiety, depression, and cognitive impairment. These manifestations often affect patients' quality of life and work capacity to varying degrees, and can severely impact life expectancy [1-2].

With the emergence of the bio-psycho-social medical model, increasing attention has been paid to patients' subjective experiences and quality of life. Patient-reported outcome (PRO) assessment tools provide effective pathways for eval-

uating quality of life and clinical efficacy [4]. This article provides an in-depth analysis of the characteristics and applicability of current OSA-PRO assessment tools domestically and internationally, aiming to provide references for further research development.

Literature Search Strategy: We searched PubMed, CNKI, Wanfang Data Knowledge Service Platform, VIP Database, and Chinese Biomedical Literature Database. Chinese keywords included: (“sleep apnea” OR “sleep-disordered breathing” OR “snoring” OR “snoring syndrome”) AND (“quality of life” OR “survival quality” OR “health status” OR “patient-reported outcome”) AND (“scale” OR “questionnaire” OR “tool”). English keywords included: (“sleep apnea” OR “OSA” OR “sleep-disordered breathing” OR “apnea” OR “snoring”) AND (“quality of life” OR “health status” OR “patient-reported outcome”) AND (“scale” OR “questionnaire” OR “tool”). The search period covered from database inception to October 2022. Inclusion criteria were: (1) adult OSA patients as study subjects; (2) published literature related to the development, revision, evaluation, and application of OSA-PRO assessment tools. Exclusion criteria were literature for which full text could not be obtained.

1. Specific Assessment Tools

Currently, there are 10 OSA-PRO specific assessment tools domestically and internationally, of which 9 were developed abroad and 1 domestically. These tools cover 1-10 domains with 1-84 items, predominantly using Likert-type response scales. Their development and evaluation employ Classical Test Theory. Table 1 compares these tools, including abbreviations, developers (first authors), years, countries, domains, item counts, scoring levels, score interpretation, psychometric properties, characteristics, and availability of Chinese versions.

1.1 Functional Outcomes of Sleep Questionnaire (FOSQ)

Developed by Weaver et al. [5] in 1997, FOSQ is a self-administered questionnaire for assessing the impact of sleepiness or fatigue on patients. It contains 5 domains with 30 items and has been translated into Swedish [6], Thai [7], Norwegian [8], and other versions. Luo et al. [9] used FOSQ, the Epworth Sleepiness Scale (ESS), and the Multidimensional Fatigue Inventory to assess quality of life, daytime sleepiness, and fatigue in 169 OSA patients to explore the relationship between fatigue and quality of life. The results showed that fatigue severity was negatively correlated with all domains of quality of life, with the OSA group experiencing more severe fatigue than the non-OSA group, indicating that fatigue has a greater impact on OSA patients' quality of life than daytime sleepiness.

1.2 Obstructive Sleep Apnea Patient-Oriented Severity Index (OSAPOSI)

Developed by Piccirillo et al. [10] in 1998, OSAPOSI is a specific quality of life assessment tool containing 5 domains with 32 items. Patients rate each item for both severity (0-5, from no problem to problem as bad as it can be) and importance (1-4, from not important to very important). Each item's score is the product of severity and importance scores, with higher scores indicating worse quality of life. Currently, OSAPOSI has no versions in other countries or regions, and lacks reports on its clinical application.

1.3 Calgary Sleep Apnea Quality of Life Index (SAQLI)

Developed by Flemons et al. [11] in 1998, SAQLI is a disease-specific instrument for assessing quality of life in OSA patients. It contains 5 domains with 84 items, where the 5th domain addresses treatment-related symptoms (used only for treated patients) and includes 28 items (the last two being blank for patient additions). This domain can be applied in clinical intervention trials to document potential negative treatment effects. Scoring for the first 4 domains is the sum of item scores divided by the number of items. The 5th domain score is calculated by selecting the 5 most important problems, reverse-scoring them, then dividing the total by 5 and weighting it. For untreated OSA patients, the SAQLI score is the sum of the first 4 domain totals divided by 4. If the 5th domain is used post-treatment, the SAQLI score is the sum of the first 4 domain totals minus the 5th domain score, then divided by 4. Higher scores indicate better quality of life. Studies show SAQLI has good reliability and validity, but its reliability requires further investigation [11-12]. The scale has been translated into Chinese [13-14], Portuguese [15], Japanese [16], Persian [17], and other versions. Venkatarayan [18] used SAQLI to assess quality of life in moderate-to-severe OSA patients before and after continuous positive airway pressure (CPAP) therapy, demonstrating significant quality of life improvements post-treatment.

1.4 Quebec Sleep Questionnaire (QSQ)

Developed by Lacasse et al. [19] in 2004, QSQ is a specific self-administered questionnaire for OSA patients containing 5 domains with 32 items. Domain scores are calculated as the sum of item scores within each domain divided by the number of items, with the total QSQ score being the average of the 5 domain scores. Higher scores indicate better quality of life. QSQ has been translated into Portuguese [20], Spanish [21], and Chinese [22], all demonstrating good psychometric properties. Huo et al. [22] translated and revised the simplified Chinese version of QSQ, evaluating its reliability and validity. Results showed good feasibility, with Cronbach's α coefficients ranging from 0.65-0.90 across domains and intraclass correlation coefficients for test-retest reliability ranging from 0.82-0.91, indicating good reliability, validity, and responsiveness for evaluating disease impact on OSA patients' quality of life and treatment

effects. Yu et al. [23] used QSQ and ESS as evaluation indicators for Han uvulopalatopharyngoplasty (H-UPPP) combined with tongue base radiofrequency ablation or tongue base traction surgery in moderate-to-severe OSA patients, showing improved QSQ and ESS scores post-surgery.

1.5 Quality of Life Questionnaire for Obstructive Sleep Apnea Hypopnea Syndrome (QOL-OSAHS)

Developed by Jin et al. [24] in 2006 based on Chinese cultural background, QOL-OSAHS contains 5 domains with 38 items. Currently, no other country or regional versions exist. Song et al. [25] used the STOP-Bang Questionnaire (SBQ) and QOL-OSAHS to clinically screen 94 suspected OSA patients, finding that QOL-OSAHS more comprehensively reflected quality of life connotations compared to SBQ, and showed significant positive correlation with polysomnography (PSG) diagnostic results as the gold standard, though its screening ability for OSA was suboptimal. Liu et al. [26] used QOL-OSAHS to assess quality of life in 46 OSA patients, showing that scores in multiple domains did not exceed 60 points, with generally low scores, an excellent quality of life rate of only 15.22%, and 54.35% of patients having poor quality of life, indicating substantial OSA impact on quality of life.

1.6 Functional Outcomes of Sleep Questionnaire-10 (FOSQ-10)

Developed by Chasens et al. [27] in 2009 as a simplified version of FOSQ, FOSQ-10 contains 5 domains with 10 items. Its functions are similar to the original scale, with high correlation between total and domain scores. Its simple operation and convenient administration allow effective evaluation of daytime sleepiness and related intervention effectiveness, making it more suitable for clinical application. FOSQ-10 has been translated into Chinese [28], Persian [29], and Spanish [30], confirming its reliability and validity. Yi et al. [31] used FOSQ-10 to evaluate daytime function in 177 OSA patients undergoing CPAP therapy to explore the impact of depressive symptoms on CPAP adherence, finding that depressive symptoms were associated with insomnia, decreased quality of life, and reduced daytime function in OSA patients, and could increase CPAP adherence by reducing daytime function.

1.7 Visual Analogical Well-being Scale (VAWS)

Developed by the Spanish Group of Breathing Sleep Disorders in 2011 [32], VAWS is a quality of life scale consisting of a 120 mm line with left and right ends representing worst and best health status, respectively. OSA patients mark their subjective health status on the line, taking less than 1 minute. Compared with other OSA-PRO specific tools, VAWS has only 1 item and lacks sensitivity to other domains, but its simplicity and time-efficiency allow evaluation of OSA patients' quality of life and treatment response (especially CPAP therapy). Currently, VAWS has no versions in other countries or regions, and lacks clinical application reports.

1.8 Mageri Obstructive Sleep Apnea Syndrome Questionnaire (MOSAS)

Developed by Moroni et al. [33] in 2011, MOSAS assesses OSA' s psychological and physiological impact on patients and CPAP treatment compliance. It contains two parts (A and B) with 23 items total. Part A evaluates OSA' s psychological and physiological impact, while Part B assesses discomfort and interference caused by CPAP treatment (applicable only to OSA patients using respiratory equipment at night for at least 1 month). Currently, MOSAS has no versions in other countries or regions, and lacks clinical application reports.

1.9 Patient-Reported Apnea Questionnaire (PRAQ)

Developed by Abma et al. [34-35] in 2017, PRAQ is a PRO assessment tool more suitable for clinical use, containing 10 domains with 40 items. Compared with SAQLI, PRAQ has simpler, more understandable items and is easier to administer, with broader coverage than QSQ. It can serve as an effective and reliable tool for comprehensively evaluating OSA patients' quality of life. However, further research is needed on OSA patients with high sleepiness levels to validate PRAQ' s sleepiness domain effectiveness [35]. Currently, PRAQ has no versions in other countries or regions, and lacks clinical application reports.

1.10 Symptoms, Tiredness, Alertness, Mood and Psychosocial Questionnaire (STAMP)

Developed by Mehta et al. [36] in 2020, STAMP is a quality of life questionnaire containing 5 domains with 12 items, using a 6-point Likert scale with scores ranging from 0-72 (higher scores indicate worse quality of life). The questionnaire is convenient and time-saving, useful not only for assessing OSA patients' quality of life but also for quantifying OSA severity to help evaluate disease burden and treatment response. Currently, STAMP has no versions in other countries or regions, and lacks clinical application reports.

2. Symptom-Specific Assessment Tools

Currently, there are 7 OSA-PRO symptom-specific assessment tools domestically and internationally, of which 6 were developed abroad and 1 domestically. These tools cover 1-6 domains with 8-28 items, predominantly using Likert-type response scales. Among them, ESS, SOS, and SQS have Chinese versions. Table 2 compares these tools, including abbreviations, developers (first authors), years, countries, domains, item counts, scoring levels, score interpretation, psychometric properties, characteristics, and availability of Chinese versions.

2.1 Epworth Sleepiness Scale (ESS)

Developed by Johns et al. [37] in 1991 for assessing subjective sleepiness, ESS is widely used in clinical practice and research, containing 5 domains with 8 items. It has been translated into Korean [38], Japanese [39], Norwegian [40], Turkish [41], and other versions, all demonstrating good psychometric properties. ESS is used not only to assess OSA patients' quality of life but also as a screening tool for OSA, being more economical and convenient than PSG for early detection, diagnosis, and treatment [42-43]. Wu et al. [44] conducted a multi-stage sampling survey of the general population across five Chinese cities to evaluate the reliability, validity, and responsiveness of the Chinese version of ESS, showing an average response rate of 97.92% across 8 items, with split-half reliability coefficient and Cronbach's α coefficient of 0.81 and 0.80, respectively, indicating good psychometric properties. Multiple Chinese versions exist [44-47], all with good reliability and validity. Zhang et al. [48] used ESS and the Pittsburgh Sleep Quality Index (PSQI) as outcome measures to compare distraction osteogenesis and bimaxillary advancement surgery for severe OSA, finding that distraction osteogenesis provided better improvement in both objective and subjective indicators for severe OSA patients.

2.2 Rotterdam Daytime Sleepiness Scale

Developed by Van et al. [49] in 1995 for assessing daytime sleepiness, this scale contains 3 domains with 16 items. The overall evaluation domain scores range from 0-3, while the other two domains use yes/no responses with scores being the sum of affirmative answers. Compared with ESS, the Rotterdam scale has broader coverage but lacks further clinical validation, resulting in limited clinical application. Currently, no other country or regional versions exist, and clinical application reports are lacking.

2.3 Snore Outcomes Survey (SOS)

Developed by Gliklich et al. [50] in 2002 for sleep-disordered breathing (SDB) patients with primary snoring symptoms, SOS is a symptom-specific tool containing 4 domains with 8 items. Since SDB affects spouses' /bed partners' sleep quality, Gliklich et al. [50] also designed a separate Spouse/Bed Partner Survey (SBPS) with 3 items. Chinese scholar Chen et al. [51] translated SOS into Chinese (CSOS) and evaluated its psychometric properties, showing a correlation of 0.82 between SOS and CSOS with good linguistic and conceptual interchangeability. Studies indicate SOS is a valid, reliable, and sensitive outcome measure for evaluating SDB patients' quality of life and as an economical, effective, and reliable follow-up tool. Picavet et al. [52] used SOS and SBPS to evaluate the safety and efficacy of Er:YAG laser SMOOTH mode treatment for adult snoring.

2.4 Sleep Quality Scale (SQS)

Developed by Yi et al. [53] in 2006 as a sleep-specific scale, SQS contains 6 domains with 28 items, where sleep restoration and sleep satisfaction domains require reverse scoring (higher scores indicate worse sleep quality). Initially developed for general population sleep quality assessment, Yi et al. [54] applied it to 40 OSA patients and 37 normal subjects in 2009 to evaluate its validity and reliability in OSA patients, showing good psychometric properties. However, the small sample size prevented comparison across OSA severity groups, and most subjects were male, requiring further large-scale studies to validate SQS reliability in OSA. SQS has been translated into Turkish [55] and Chinese [56]. The Chinese version (SQS-C) contains 4 domains (daytime dysfunction, sleep onset difficulty, wake-up difficulty, sleep restoration) with 23 items. Chen et al. [56] surveyed 522 Chinese drivers using SQS-C, showing Cronbach's α coefficients of 0.60-0.93 for overall and domain scores, similar to the original scale, confirming good psychometric properties for measuring sleep quality in Chinese drivers.

2.5 Time of Day Sleepiness Scale (ToDSS)

Developed by Dolan et al. [57] in 2009 for assessing daytime sleepiness, ToDSS contains 1 domain with 8 items. Item content is similar to ESS but evaluates sleepiness at three different time points during the day (morning [before noon], afternoon [noon to 6 PM], evening [after 6 PM]). The scale has three columns, with patients scoring each item from 0-3 ("0" = never doze, "3" = high chance of dozing), allowing comparison across columns and taking about 5 minutes total. ToDSS helps patients pinpoint specific times of sleepiness rather than vaguely recognizing excessive sleepiness, and can also assess OSA patients' response to CPAP therapy. Currently, ToDSS has no versions in other countries or regions, and lacks clinical application reports.

2.6 Sleepiness-Wakefulness Inability and Fatigue Test (SWIFT)

Developed by Sangal et al. [58] in 2012, SWIFT is a symptom-specific tool for assessing wakefulness ability and pathological sleepiness, fatigue/tiredness/lack of energy symptoms in sleep disorder patients. It has two parts (A and B) with 12 items total. Part A (6 items) relates to patients' ability to stay awake, while Part B (6 items) relates to the impact of fatigue/tiredness/lack of energy. SWIFT total score is the sum of Parts A and B. Studies show SWIFT is better than ESS at distinguishing normal subjects from OSA patients across two age groups and can compensate for limitations of ESS and other sleep assessment tools. Therefore, SWIFT can be used alongside ESS when evaluating daytime consequences of sleep disorders. Currently, SWIFT has no versions in other countries or regions, and lacks clinical application reports.

2.7 Traditional Chinese Medicine Sleepiness Assessment Scale

Developed by Xu et al. [59] in 2013, this TCM syndrome scale evaluates sleepiness status in OSA patients, containing 2 domains (symptoms and signs) with 28 items that identify three common TCM syndrome types: phlegm-dampness, damp-heat, and blood stasis. Except for tongue coating and pulse, items are scored as: very severe (4 points), severe (3 points), moderate (2 points), mild (1 point), or none (0 points). The scale effectively evaluates OSA patients' sleepiness severity and can summarize common TCM syndrome types through patients' symptoms and signs. Currently, no other country or regional versions exist, and clinical application reports are lacking.

3. Future Directions and Outlook

This study shows that 17 OSA-PRO assessment tools currently exist domestically and internationally, mostly developed abroad, covering domains including symptoms, daily activities, social activities, and psychological emotions. Their development and evaluation use Classical Test Theory, providing foundations for OSA patients' quality of life assessment and clinical efficacy evaluation. However, some tools have limitations. We propose the following recommendations:

3.1 Conduct Psychometric Property and Methodological Quality Evaluation Studies of OSA-PRO Tools

Currently, numerous OSA-PRO tools exist, but some (e.g., STAMP, PRAQ, QOL-OSAHS, OSAPOSI, TCM Sleepiness Assessment Scale) lack large-sample studies, have limited clinical application, and have not gained domestic/international recognition. Their reliability, validity, and responsiveness require further evaluation. We recommend conducting psychometric property and methodological quality evaluation studies to screen high-quality tools. The Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) is a commonly used tool for evaluating PRO measurement properties and methodological quality, applicable for systematic reviews of PRO tools to provide recommendations [60]. Abma et al. [61] used COSMIN in 2016 to evaluate 22 OSA-PRO tools, finding that OSAPOSI, MOSAS, QSQ, and SAQLI had good content validity and were more suitable for clinical use; ESS, though widely used, was of moderate quality, while SWIFT could potentially replace ESS.

3.2 Combine Classical Test Theory and Modern Test Theory to Develop, Revise, and Evaluate OSA-PRO Tools

Current OSA-PRO tool development and evaluation predominantly use Classical Test Theory (CTT). While CTT has simple models and mature theory, it has limitations including imprecise error estimation, performance indices de-

pending on specific examinee samples, and examinee evaluation depending on specific item combinations and numbers [62]. To overcome CTT limitations, modern measurement theories such as Generalizability Theory and Item Response Theory have emerged. Combining CTT with modern measurement theories to evaluate OSA-PRO tools' psychometric properties and guide subsequent development, revision, and evaluation can achieve complementary advantages and improve tool quality [62-64].

3.3 Strengthen Minimal Clinically Important Difference (MCID) Research for OSA-PRO Tools

With widespread PRO tool use in clinical efficacy evaluation, how to reasonably use scale scores to determine and interpret clinical results has become a research hotspot. Even statistically significant measurement differences may not represent clinical significance [65]. In this context, Guyatt et al. [66] proposed MCID, which Jaeschke et al. [67] defined in 1989 as the smallest change value patients consider beneficial, without considering side effects and cost burden. MCID provides basis for judging clinical significance of measurement results, sample size estimation, and clinical decision-making [68]. Currently, MCID research for OSA-PRO tools is scarce and originates from abroad [69-70]. MCID is influenced by disease characteristics, population demographics, and language environment [71]. Therefore, strengthening MCID research for Chinese populations is necessary to better utilize assessment tools in clinical efficacy evaluation.

3.4 Develop OSA-PRO Tools Highlighting Traditional Chinese Medicine Clinical Efficacy Characteristics

PRO assessment tools can comprehensively evaluate patient health status across different domains and assess patients' self-perceived single symptoms, with information directly from patients without involving others. This process aligns with TCM concepts of "people-centered" and "holistic view" [72]. Existing OSA-PRO tools were mostly developed based on Western cultural backgrounds, lacking cross-cultural adaptation for Chinese populations and unable to reflect TCM clinical efficacy characteristics. Currently, OSA-PRO tools developed based on Chinese cultural background include QOL-OSAHS and the TCM Sleepiness Assessment Scale. While the latter incorporates TCM elements, its domains are singular and cannot comprehensively evaluate OSA patients' quality of life. Therefore, developing OSA-PRO tools that can comprehensively evaluate OSA patients' quality of life while highlighting TCM clinical efficacy characteristics is particularly necessary.

In summary, this article systematically reviews the psychometric characteristics and applicability of existing OSA-PRO assessment tools. Results show that current tools are mostly developed abroad, covering symptoms, daily activities, social activities, and psychological emotions. We recommend future research focus on evaluating psychometric properties and methodological quality of OSA-PRO tools; strengthening MCID research; and developing OSA-PRO tools that

highlight TCM clinical efficacy characteristics.

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