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Self-reporting to Measure Treatment Adherence in Patients with Chronic Obstructive Pulmonary Disease: A Systematic Review

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Abstract*— Objective:** *The purpose of this systematic review was to conduct asynthesis of a set of tools to measure adherence to treatment suitable for COPD patients, treatment adherence level of patients with COPD, and provide recommendations for nurses to determine appropriate treatment adherence self-report scales in COPD patients.* ***Material and Methods: *Predefined keywords were identified by using a PICO format. Keywords included "Chronic obstructive pulmonary diseases" or "treatment adherence self-report scale". Ten articles met all eligible criteria for review from a total of 833 published studies.* ***Results:*** *Among the 10 articles, most studies were conducted in Europe (50%) and Asia (30%) and used a cross-sectional study design (90%). The self-reported scales of treatment adherence in COPD patients icluded MARS (20%), MMAS (50%), TAI (10%), MTA (10%) and self-report adherence quesionnaire (10%). The level of non-adherence to COPD treatment ranged from 16.5% to 74.1%.* ***Conclusion:*** *Several self-reported scales that are most frequently used in COPD patient treatment adherence research weer evaluated for this review. Before selecting any adherence scale, several factors must be taken into account.*

***Keywords*—** *Chronic obstructive pulmonary disease, systematic review, treatment adherence.*

I. INTRODUCTION

Globally, there are about 3 million deaths annually due to chronic obstructive pulmonary disease (COPD). The frequency of COPD is increasing due to smoking in developing countries, an aging population, and environmental factors. The frequency increases by 2060, with about 5.4 million COPD-related deaths [1]. In Vietnam, the prevalence of COPD is estimated at 6.7%, the highest in Southeast Asia. Of these, more than half of those infected have experienced at least one severe episode [2]. Currently, it is not possible to completely cured of COPD, but early treatment and adherence to the medical staff's instructions can reduce symptoms, slow down lung damage, and improve patients' quality of life [1].

Treatment adherence is defined as the active and voluntary cooperation between the patient and healthcare providers in taking the prescribed medication (including the duration, dose, and frequency of administration), following a reasonable diet, and/or changing a healthy lifestyle in accordance with their disease. However, improving the quality of life of COPD patients requires patients to commit to treatment over a long time period. Numerous studies have shown that long-term adherence to chronic disease is suboptimal in real-world settings, and it is estimated that only 50% of patients respond to correct adherence [3]. Non-adherence to treatment has significant impacts in terms of increased hospitalization and exacerbation rates, decreased quality of life, increased number of emergency visits, increased number of days off work due to COPD, and increased morbidity and mortality rate as well as cause many complications for patients [1]. Evaluating adherence remains a challenge in the clinical assessment of patients. In clinical research, the use of different adherence assessment methods will yield different results. Currently, measuring adherence is a challenge in the clinical assessment of patients and in clinical trial studies conducted by healthcare professionals. This challenge may be due to lack of consistency in the methodology for assessing compliance in studies of COPD, therefore, the use of different compliance assessment methods will give different results. Additionally, most medications used for COPD are inhaled, and inhaled medications have different effects on the assessment of adherence than oral medications [1].

Although the subjective assessment method often gives a higher compliance result than the reality, most studies use it to determine the level of treatment adherence because of the timesaving and cost advantages [1],[3]. From our review of the literature, there are many scales used to assess adherence in patients with COPD, but choosing the optimal scale ensures accuracy and reliability in practice and research. Therefore, a systematic review and quality assessment of studies are needed to provide evidence on measuring adherence across countries. This is significant to the process of applying evidene to clinical trials. care and follow-up of patients. The systematic review study was conducted with two main objectives: 1) synthesize a set of tools to measure adherence to treatment suitable for COPD patients; and 2) provide recommendations for nurses to determine appropriate treatment adherence self-reported scales in COPD patients.

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II. METHODS

Search strategies

The studies used self-report methods to measure adherence in patients with COPD from PubMed, Medline, Ovid/Cochrane Library, Google Scholar data sources updated from December 2011 to December 2021.

Search strategy: the research team used the PICO questionnaire to determine the keywords of the search query, included:

• P (population): COPD/ Chronic Obstructive Pulmonary Diseases
• I (intervention/method): Self-report toolkit for measuring adherence
• C (comparison/control regimen): none
• O (outcome/output): Level of compliance, factors related to treatment adherence

However, the search stages are shown in the Table 1.

TABLE 1. Search Booleans

Chronic Obstructive Pulmonary Diseases OR "COPD OR "Chronic Obstructive Lung Disease" OR "COAD" OR "Chronic Obstructive Airway Disease" OR "Airflow Obstruction, Chronic" OR "Airflow Obstructions, Chronic" OR "Chronic Airflow Obstructions" OR "Chronic Airflow Obstructions"
AND
adherence OR compliance OR concordance OR cooperation OR noncompliance OR "non compliance" OR non-compliance OR "patient compliance" OR nonadherence OR non-adherence OR "non adherence" OR "medication adherence" OR "guideline adherence" OR "patient compliance" OR "COPD medication adherence scale" OR "evaluation of adherence" OR "medication adherence scale" OR "oral medication adherence" OR "treatment adherence" OR "diabetes medication adherence scale" OR "assessment" OR "evaluation" OR "assessing" OR "Adherence to treatment"

Research selection process

Two researchers read the titles and abstracts of the studies independently. The results were then cross reviewed, discussed, agreed, or consulted by a third party to come to a consensus on the final selected articles. Studies that met the inclusion criteria and were not included in the exclusion criteria were included in the systematic review. The specific search process is shown in Fig 1.

Inclusion criteria:

Articles with research design: cross-sectional description; The studies involved adults with a diagnosis of chronic obstructive pulmonary disease (aged 18 years and older) receiving outpatient treatment in a health care facility regardless of gender or race; related research using the adherence assessment toolkit; use English language.

Exclusion criteria

Related studies on subjects with COPD with the children, pregnant women; studies evaluating treatment adherence when patients are hospitalized due to an exacerbation or being treated in the hospital for an exacerbation; research using treatment adherence assessment in conjunction with family members or medical staff; research with inappropriate research methods (systematic review or meta-analysis) or secondary research; study published before December 2011.

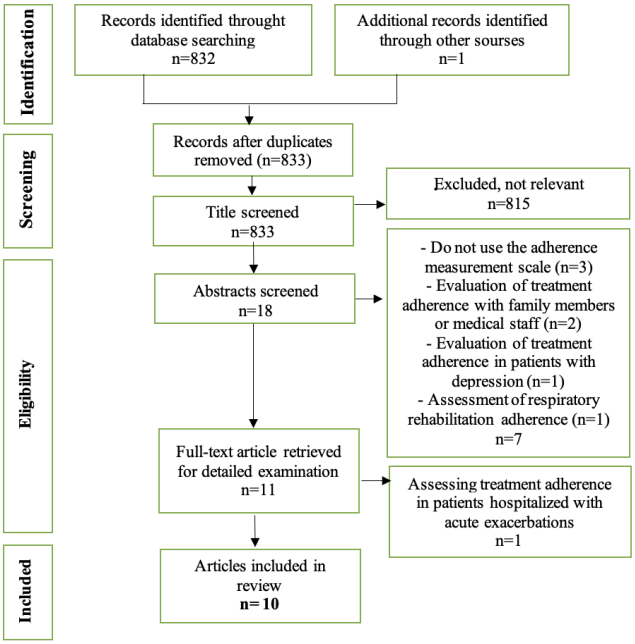

Figure 1. PRISMA flow diagram - the search and selection process using on this review

Quality assessment

The quality of all eligible studies was assessed using the Evidence-Based Management Center Evaluation Checklist for Observational Studies. Studies that achieve at least 6 of the 12 criteria defined by the rating scale are considered to be of good quality and included in the overall review [4].

Data extraction

Of the 833 studies initially found through the four databases, we used 10 articles that met the criteria as well as quality assurance. The research team evaluated the following information to find and extract content that was relevant to our research objectives: author, year, country of study; research design; general characteristics of the research object; toolkit for measuring adherence to treatment; and factors related to treatment adherence.

Data analysis

Zotero software was used to store citation information from studies and to process duplicate data. Documents from electronic data sources were also downloaded directly to Zetoro. Duplicates were detected and removed. Each study was guaranteed to count only once with a specific code. The aggregated data was analyzed according to the usual statistical processing method of Excel.

III. RESULT

Study characteristics

Out of a total of 833 studies found, 10 were included in this systematic literature review. Regarding study sites, three

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studies were conducted in Asia (30%), five studies in Europe (50%), and two studies in the Americas (20%) (see Table 2). Most of studies did not carry out a scale adaptation process through validation tests or adequate psychometric tests. Most of the selected studies were cross-sectional research designs (90%) (n = 9) with an additional qualitative study (10%) (n=1). All were primary studies measuring treatment adherence in COPD patients.

Study participants were diagnosed with COPD for at least 1 year and undergoing outpatient treatment. The average age of the study participant was 66.5 ± 10.2. Among those studies, six studies had a higher proportion of men than women, while in Kokturk's study (2018), 81.1% of the participants were male [5]. In the study by Elander and Gustafsson, female participants accounted for 78.3% [6]. The number of participants varied significantly between studies, the largest number of patients participating in Montes de Oca study [7], was 795 people while in the Elander study, it had the fewest participants (n=23) [6].

TABLE 2. General characteristic of included studies

No	Author and research design	Country	Self-reported scale	Participant characteristic/ Setting	Duration of study (months)	Limitations related to the adherence scale
1	Ierodiakonou et al. [13] (2020) Cross-sectional study	Greece	TAI-12	257 COPD patient; being classification disease stage based on CAT and mMRC scale. Community	12	Not included in the study
2	Elander et al. [6] (2020) Cross-sectional study	Sweden	MARS-5	23 COPD patients ≥ 18 aged, using inhaled medicine. Hospital	3	Recall bias
3	Duarte et al. [12] (2019) Cross-sectional study	Portugal	MTA	303 COPD patients ≥ 40 years; using inhaled medicine. Outpatient clinic	14	Not included in the study
4	Jarab et al. [9] (2019) Cross-sectional study	Jordan	MMAS-4	133 COPD patients ≥ 35-year-old; being diagnosed oat least 1 year; FEV1 level over 30% Outpatient clinic	5	Overestimated answer, and social bias
5	Kokturk et al. [5] (2018) Cross-sectional study	Turkey and Saudi Arabia	MMAS-8	405 COPD patients ≥ 40-year-old; being diagnosed over 1 years; being treated with at least 1 COPD maintenance medication. Hospital and outpatient clinic	3	Overestimated answer
6	Montes de Oca et al. [7] (2017) Cross-sectional study	7 Latin American countries	MMAS-8, and TAI-10 questionnaire	795 COPD patients ≥ 40-year-old; being diagnosed over 1 years, having a FEV1 /FVC < 0.7. Community	12	Two items in the TAI-10 questionnaire were not available, leading to inability to evaluate non-adherence
7	Krauskopf et al. [8] (2015) Cross-sectional study	America	MARS-10	591 COPD patients ≥ 55-year-old; being diagnosed by medical experts	20	Recall bias from patient's reports
8	Khdour et al. [10] (2012) Qualitative study	Northern Ireland	MMAS-4	173 COPD patients over 45-year-old; being diagnosed at least 1 year. Community clinic	1	Not included in the study
9	Ágh et al. [11] (2011) Cross-sectional study	Hungary	MMAS -4	250 COPD patients were being diagnosed at least 1 year; over 45-year-old; using drug treatment. Outpatient clinic	11	Overestimated answer
10	Takemura et al. [14] (2011) Cross-sectional study	Japan	Self-report quesionnaire	55 COPD patients visit the clinic every 1-3 months, using inhaled medicine over 12 months. Community clinic	5	Not included in the study

TAI= Test of the adherence to inhalers; MMAS-4/8= Morisky Medication Adherence Scale with 4 or 8 questions; MARS-5/10= Medication Adherence Reporting Scale with 5 or 10 items; MTA= Measure of Treatment Adherence

Self-reported treatment adherence scales for COPD patients

There were eight self-reported scales, including MARS (20%), MMAS (50%), TAI (10%), MTA (10%) and self-report adherence questionnaires (10%); all scale were used to assess treatment adherence of COPD patients (see Table 2); and the result of scale validated also being shown in Table 3. Additionally, the systematic review also assessed treatment adherence levels in COPD patients (see Table 4).

Medication Adherence Reporting Scale (MARS-5; MARS-10)

The Medication Adherence Reporting Scale-5 (MARS-5) and Medication Adherence Reporting Scale-10 (MARS-10) were used in two articles [6],[8]. Both studies conducted in out-patients within period of 3 - 20 months. This review found that one article used the MARS-10 scale that has been validated in COPD patients by test-retest reliability process.

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There are different versions of MMAS-10 by countries and languages for COPD patients. Internal consistency values or Cronbach alpha of MARS-10 for COPD patients ranged from 0.85 to 0.86. Additionally, applying MARS-5 to assess treatment adherence in COPD patients, 69.6% (n=16) of participants were adherent to their treatment [6]; while in a study using MARS-10, 58.2% reported non-adherence to treatment [8]. Both studies used the same scale.

TABLE 3. Self-reported scale for treatment adherence in COPD patients

No	Self-reported adherence scale/ Original language	Participant in initial validation study	The Cronbach's value in initial study	Validation processes in the COPD population	The Cronbach's value COPD patients (Country)
1	MARS-5 English	Schizophrenia	0.75	Not validated in COPD patients	N/A
2	MARS-10 English	Chronic disease	0.85	Validated in COPD patients by test-retest reliability process	0.86 (Spanish)
3	MMAS-4 English	Hypertension	0.61	Validated in COPD patients and translated to the Jorrdan language; and Hungary language	0.61
4	MMAS-8 English	Hypertension	0.83	Validate and translated into Turkish and Arabic	N/A
5	MTA Portuguese	COPD	0.74	Validate and translated into Portuguese	0.74
6	TAI-10 and TAI-12 English	COPD	0.86	N/A	N/A
7	Self-report adherence quesionnaire English	COPD	0.7 COPD	Internal reliability was done by using KR20	N/A

N/A= not available; TAI= Test of the adherence to inhalers; MMAS-4/8= Morisky Medication Adherence Scale with 4 or 8 questions; MARS-5/10= Medication Adherence Reporting Scale with 5 or 10 items; MTA= Measure of Treatment Adherence

Morisky Medication Adherence Scale (MMAS-4 and MMAS-8)

The MMAS questionnaire was widely used to measure adherence to treatment in COPD patients. Out of 10 studies, there were five studies using the MMAS scales, of which 3 used the MMAS-4 scale [9-11], and 2 studies used the MMAS-8.[5,7] Most of the studies were conducted over a period of 1 to 12 months. The validity of the MMAS questionnaire (4 items or 8 items) in the studies was conducted by the author or by using the results from previous studies. Both versions of the MMAS scale was translated in across countries and languages to measure adherence in people with COPD. The internal consistency values or Cronbach alpha of MMAS for COPD patients was 0.61 (Table 2). When using MMAS-4 to measure treatment adherence in people with COPD, the percentage of non-adherence with treatment ranged from 29.5 to 61.7% and missing dose or forgetting medication are common errors; studies that used MMAS-8 expressed with over 20% to 49.2% of participants reported low treatment adherence.

Measure of Treatment Adherence (MTA)

The Measure of Treatment Adherence (MTA) was used to measure adherence to inhaled medication [12]. The MTA was validated for the Portuguese population in 2001 with a Cronbach's alpha of 0.74. It comprises a seven-item questionnaire that reflects typical non-treatment adherence behavior patterns. The scale used was a Likert scale with 6-points for each item and a total score ranging from 6 to 42 with higher scores indicating higher self-reported treatment adherence. When the author named Duarte applied this scale to assess treatment adherence of COPD patients for 14 months, they recognized that almost 17% of patients did not adhere to their medication.

TABLE 4. Level of treatment adhernce factors affecting adherence to treatment in COPD patients

No.	Studies	Level of treatment adhernce
1	Ierodiakonou et al. [13]	74.1% of patients with COPD reported poor adherence to treatment, of which intentional non-compliance was 69.5%
2	Elander et al. [6]	69.6% reported adherence to medications
3	Duarte-de-Araújo et al. [12]	16.5% of patients did not adhere to the medication
4	Jarab and Mukattash. [9]	61.7% of non-compliance with medication, missing dose or forgetting medication are common errors
5	Kokturk et al. [5]	49.2% reported low drug adherence (MMAS-8 < 6)
6	Montes de Oca et al. [7]	51% had high compliance, 29.1% medium and 19.9% low
7	Krauskopf et al. [8]	58.2% reported non-adherence to treatment
8	Khdour et al. [10]	29.5% reported low medication adherence
9	Ágh et al. [11]	58.2% reported medication adherence
10	Takemura et al. [14]	54.5% reported good compliance

MMAS-8= Morisky Medication Adherence Scale with 8 questions

Test of the adherence to inhalers (TAI-10; TAI-12)

The Test of Adherence to Inhalers (TAI) has two different versions [7],[13]. The TAI-10 was designed to identify non-adherent patients and the level of non-adherence. Each of the 10 questions on the TAI questionnaire had a score that varied from 1 to 5, and the overall score was between 10 and 50. Adherence was given a good (score of 50), moderate (score of 46-49), or subpar (score of 45) rating [7]. The TAI-12 scale included two additional items for practitioners to identify patients with low adherence. Each item was graded with either 1 or 2 points (poor or good understanding of the regimen and/or breathing technique), and they may provide information on the patient's pattern of non-compliance, such as occasional, intentional, or unconscious non-compliance. The Cronbach's alpha for the scale was 0.86. Two articles

applied the TAI scale with20% to 74.1% of COPD patients reporting poor adherence to treatment [13].

Self-report adherence questionnaire

The adherence questionnaire included the four questions concerning the use of inhaled controller medications. For every question, there were five different ways to respond (1-most of the time to 5-none of the time) [14]. The self-reported adherence score was determined from the mean of the four questions. Higher scores imply better adherence to the inhalation regimen; more specifically, a score >= 4 indicates patients have strong adherence, while a score 4 indicates patients have poor adherence. Internal reliability of original scalse was done by using KR20 with the score accounted at 0.7. When Takemura used this scale to test treatment adherence of COPD patient, the results indicated that 54.5% of participants reported good compliance [14].

IV. DISCUSION

In this systematic review, five different groups of scales selected from 10 studies to assess the degree of adherence, mainly drug adherence, of patients with COPD were identified.

Researchers using the scales emphasized that the properties of the question, the response to the scale, and the measuring period may affect the outcomes [15]. Therefore, psychometric testing is a pivotal step. The majority of the studies employed validity tests that have already been conducted by other researchers on the same or different populations and contexts that are distinct from the target group (Table 2). Population variances during psychometric testing may impair adherence measurements in COPD patients.

All studies agree that the use of questionnaires for patients to self-assess the level of treatment adherence is the easiest method to apply, but this method also has limitations. Patients may report drug use more frequently to appease healthcare professionals. The drug compliance questionnaire is based on such topics as: do you forget to take your medication, change the dose on your own, stop or skip a dose, have trouble remembering to take your medication or stick to the prescribed dose, etc. However, in order to limit the subjectivity of the research subjects, the questionnaires to assess drug adherence also need to be diverse in the number of questions to avoid errors caused by patients using positive answers for heathcare provider satisfaction. For example, in the study by Kokturk et al [5], Ágh et al [11], and Montes de Oca et al [7] using eight questions were used (MMAS) while the study by Jarab and Mukatash also using MMAS selected only four questions related to patient's medication use [6].

During the study of treatment adherence, each case must be defined as compliance or non-compliance, which is fundamentally dependent on the measurement method used and the time for assessing the adherence. To assess and classify the level of treatment adherence, most of the studies are based on the answer "Yes" or "No" with the answer "yes" getting "1 point" and the answer "no" receiving "0 point" (Kokturk et al; Khdour et al; Agh et al; Jarab and Mukattash; Oca et al) [5],[7],[9-11]. Meanwhile, some other studies use a 5-Liket scale that ranged from "1" (always) to "5" (never) [6],[8]. However, other studies used a 6-Liket scale ranging from "1" (always) to "6" (never) [13]. This difference may beappropriate because each study was conducted on patients in different countries. Local conditions mayaffect the view of treatment adherence of COPD patients about the levels and ways of medical use.

Studies on treatment adherence have been carried out in different countries, but in general, the level of adherence to medication of COPD patients is low. When comparing between ten studies, each result expressed a significant difference in the rate of treatment adherence. For example, the study of Ágh et al. reported an adherence levelat 58.2% [11], while the Duarte-de-Araújo et al. study reported 16.5% of patient adherence to treatment [12]. It is possible that patients did not clearly understand the disease, impacting their ability to adhere to treatment. Another reason may be that while patient may be knowledgeable about the diseasethey may lack a positive attitude toward treatment and require more encouragement and reminders, especially from relatives. There are also cases where the patient has knowledge and a positive attitude about treatment, but due to heavywork schedules, age-related issues, forgetfulness, lack of encouragement and reminders from family members adherence becomes a challenge. Healthcare providers should conduct their own assessments to determine the level of treatment adherence and establish a trusting relationship with the patient and family to improve adherence.

In this review, we also suggest some recommendations that could be applied to treatment adherence studies: (1) select a self- report treatment adherence scale that has already been validated in an original article; or (2) use appropriate treatment adherence scales that have similar population characteristics such as language and sociodemographic conditions.; 3) the best choice is that conduct scale validation on the study's population. However, this review has some limitations. First, the studies included in the review were written in English, excluding the possibility for strong studies written in other languages. Second, all studies related to adherence to treatment in COPD patients focus on only one type of adherence, drug adherence. However, WHO (2003) defines adherence broadly to include the patient's voluntary cooperation in taking the prescribed medication (including duration, dose, and frequency), implementing a healthy diet, and/or making appropriate lifestyle changes. Finally, the studies in this systematic review were weighted the same regardless of sample size; so smaller studies tend to report lower adherence, and this could lead to bias.

V. CONCLUSION

The review provide insight into the different types of self-report scales that can be applied to patients with COPD even if it is not a comprehensive overview of all methods used in adherence studies. The MMAS self-rating scale is most commonly used in patients with COPD; but psychometric testing is needed to perform before conduct in other study.

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