

# Assessment methods and therapy adherence scales in hypertensive patients: A literature review.

Isabel C Pinto<sup>1\*</sup>, Marta Pereira

Department of Diagnostic and Therapeutic Technologies, School of Health Sciences, Polytechnic Institute of Braganca, Av D. Afonso V, 5300-121, Braganca, Portugal

## Abstract

**Background:** Arterial Hypertension is a chronic disease whose control is directly related to the patient antihypertensive therapy adherence. It is therefore important to know and understand the methods and scales of evaluation of adherence. Thus, the aim of this review is to identify assessment methods and therapy adherence scales in hypertensive patients.

**Methods and Findings:** This study is a literature review of published studies from 1986 to 2015, held in electronic databases Web of Science and PubMed. For this research were selected 22 studies were identified that corresponded to inclusion criteria. This review was conducted from February to May 2015. To measure and assess the patient adherence to prescribed treatment, different methods were found, such as direct: biological analysis and adding a marker to ingested medication; and indirect methods: patient diary, questionnaires or structured interviews, drug exemption of registration pharmacy, electronic monitoring and pill counts.

**Conclusion:** The different methods currently available for assessing therapy adherence only provide an estimate of the existing behavior of patient compliance.

**Keywords:** Arterial hypertension, Hypertensive patients, Therapy adherence, Adherence assessment methods, Adherence scales.

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## Introduction

Arterial Hypertension (AH) is a chronic disease that requires treatment for life. Their control is directly related to the degree of patient adherence to therapy that is indicated to him [1,2].

Failure to medication adherence is associated not only to the act of taking the prescribed medicines, but also in the way the patient leads the treatment indications [3].

To identify, evaluate and measure patient adherence to the prescribed treatment, several direct and indirect methods have been developed and used [2]. Direct methods are characterized as the dosage of the active substance/drug metabolite and indirect methods include strategies as questionnaires and interviews, among others [2,4].

The objective of this review is to identify assessment methods and therapy adherence scales in hypertensive patients.

## Methodology

The present Mini Review consists of a literature review, based on search of articles in Web of Science and PubMed Search engines, in which the following keywords were used: Arterial hypertension; Hypertensive patients; Therapy adherence; Adherence assessment methods; Adherence Scales. Additionally, in order to increase the search results, were also included in this review websites of official entities linked to health. The period defined for the search of articles was from 1986 to 2015, in Portuguese or English language. The inclusion criteria used were scientific articles and reports that were considered potentially to study aim. After screening by reading

the abstracts and full articles, to evaluate if they corresponded to the objective under study, were included a total of 22 articles and reports. This review was carried out from from February to May 2015.

## Results

The World Health Organization estimates that 30% to 40% of the world population suffers from hypertension. Portugal is no exception to this reality [5], because there are about two million hypertensives [6]. This organization has defined high blood pressure as "a disease characterized by a chronic elevation of systolic blood pressure (SBP) and/or diastolic blood pressure (DBP)" [7]. Drug treatment and non-pharmacological help to maintain the blood pressure (BP) below 140 mmHg for SBP and 90 mmHg for DBP [8].

Being chronic can be controlled, but never cured. Therefore, it requires lifelong treatment. The stability of its values is directly related to the degree of patient adherence to therapy that is indicated to him [2].

Failure to medication adherence is associated not only to the act of taking the prescribed medicine, but in the way the patient leads the treatment [3], being influenced by several factors such as age, socioeconomic status, level of education, knowledge of the disease, the cost of medicine, the timing of doses, dietary restrictions, leisure and work, among others [2].

To measure and evaluate patient adherence to prescribed treatment, various direct and indirect methods have been developed and used [1].

## **Direct Methods**

They seek to verify that the medicine has indeed been ingested [9,10]. There are two distinct ways to obtain such evidence [9].

### **Biological analysis**

It consists of blood test or urine/feces to detect ingested drug or its metabolites [9]. It is objective but there may be variations in the metabolism of the drug which also alters the concentrations of the drug / metabolites [10].

### **Adding an indicator to ingested medication**

It is the addition of an innocuous substance to the body such as B complex) [9]. It is an expensive evaluation [10].

## **Indirect Methods**

These methods include simple strategies and, when used in a standardized manner, can give valuable information on the degree of adherence to treatment and therefore are useful in clinical practice [11].

The main indirect methods require the patient's cooperation.

### **Patient diary**

The patient is oriented to register, daily, all events related to the use of medicines [12] and if the book is filled properly, it could provide important information [9] (time and amount used of each medicine, difficulties encountered, external situations that interfered the time to take the medicines, adverse reactions and other) [12] can be correlated with non-adherence [9]. The disadvantage of this method is that the registers can be easily changed by the patient.

### **Structured questionnaires or interviews**

Also known as psychometric measures of treatment adherence [13], they are methodological tools that assess user behavior beyond the empirical management data obtained by simple observation of everyday conduct [4]. These have been the type of indirect methods most commonly used [4,14], especially over the last decade [4]. It is a fast, simple and inexpensive method but the results can be distorted by the patient and depending on the questionnaire it can be just feasible in practice because of its length [10].

In this category, we highlight the questionnaires Morisky-Green (TMG) [15], Haynes and Sacket, Brief Medication Questionnaire (BMQ) Questionnaire of Adherence to Medications - Team Qualiaids (QAM-Q), Hill-Bone compliance scale, Measure adherence to treatment (MAT) as well as questionnaires of food adhesion and adherence to physical activity.

The method of Haynes and Sacket is based on a question to the patient, whose affirmative response classifies it as non-adherent [4,11].

The BMQ questionnaire is an instrument divided into three areas that identify barriers to adherence as the regime (covering the difficulties the patient to name the medication and doses used, in addition to the reporting of missing days and / or doses), beliefs (the presence or not of drugs that do not work well, or cause any adverse reaction) and memory in relation to medical treatment

in the patient's perspective (refers to the presence of a scheme of multiple daily doses and the account of the difficulties the patient to take the medication) [1,14], and a score greater than or equal to one, in any of these indicates positive potential for non-adherence to treatment, and the total score of the questionnaire, in which no positive response indicates adherence to treatment, a positive response suggests the likely accession treatment, two answers and three or more positive indicate, respectively, likely poor adherence and low adherence to treatment [16]. In the original study, the domain had a sensitivity of 80% and specificity of 100% [1].

The QAM-Q is a tool designed to address the act (if the individual takes and when he takes medicines), the process (as he takes the medicine in a seven-day period, changes doses, taking the wrong way, or if he pauses) and the result of joining (if the pressure is controlled) [4], which makes this questionnaire has three questions from which you can build three non-accession measures: 1) Proportion of dosages taken - continuous measure of the act to adherence, 2) process of taking pills - ordinal measure of the process of adherence, 3) outcome - dichotomous outcome measure to adhere [1,4]. In the presence of one of these conditions the respondent is considered non-adherent [4], it is only considered adherent an individual who reports having taken 80% to 120% of the prescribed dose correctly [17]. The original study had a sensitivity of 62.5% and specificity of 85.7% [1].

The scale of Hill-Bone assesses user behavior on three important behavioral domains to treat high BP: 1) reducing sodium intake, 2) number of visits and 3) taking the medication. This scale consists of 14 items in three subscales [18].

TMG it is a measure built in 1986 and constitutes the most widely used instrument to measure compliance with the use of medications [4]. The fundamental theory of the measure states that the inappropriate use of drugs occurs in one or all of the following forms: forgetfulness, carelessness and stop the medication when feeling better or worse [1]. It is easy to measure, date, with a relatively small number of questions understandable that provide verification of the user's attitude towards taking medicines. It is a qualitative instrument and the questions are timeless [4]. The original version had low sensitivity, 43,6% and reasonable specificity, 81,4% and consists of four questions: 1) Do you ever forget to take your medicine? 2) Do you sometimes neglect to take your medicine? 3) When you feel better, you sometimes stop taking your medicine? 4) Sometimes if you feel worse when taking the medication, you stop taking it? [14]. The affirmative answer to any of these questions classifies the individual as non-adherent [11].

In studies conducted subsequently to its creation, the TMG is not efficient to relate controlled BP levels and positive attitude towards taking the medicinal product [1]. This lack of correlation with clinical outcomes Morisky motivated to expand this questionnaire, adding four more questions to the originals. Each of the eight items of Morisky Medication Adherence Scale (MMAS-8) measures the specific behavior of taking medicine, identifying aspects that contribute or not for adherence [11]. This new questionnaire is more reliable [1] and sensitivity compared to the one with four items. The degree of adhesion was determined in accordance with the resulting score

of the sum of all correct answers: high adherence (eight points), average adherence (six to <eight points) and poor adherence (<six points) [19].

The MAT contains the following questions: 1) Have you ever forgotten to take medication? 2) Have you ever been careless with the hours of taking medication for your disease? 3) Have you ever stopped taking medications for your disease, on your own initiative, because it was better? 4) Have you ever stopped taking medications for your illness on your own initiative, for having felt worse? 5) Have you ever taken one or more tablets for your disease on your own initiative, after having felt worse? 6) Have you ever interrupted the treatment for your illness for letting your medicines end? 7) Have you ever stopped taking medication for your illness for some other reason other than the indication of the doctor? [3]. Items 1, 2, 3 and 4 were adapted Morisky [13].

Some researchers were concerned to evaluate the psychometric characteristics of questionnaires that propose to measure the level of physical activity [20] and food accession [11].

Within the various types of questionnaires to assess the level of physical activity, the International Physical Activity Questionnaire (IPAQ) [14], is the instrument that has been most widely used [11], containing reasonable measurement properties for monitoring levels of physical activity [20]. This comprises four presentations, two in the long form and two in short form [11], containing data from physical activity habits of moderate to vigorous intensity within different areas of life (work, household chores, transportation and leisure) [20] thus classifying individuals as sedentary or active [14].

Once inside the methods of assessment of food accession, the instruments available in the literature [11], stands out the Food Frequency Questionnaire Sodium (QFASó), which evaluates the consumption of foods with high sodium content, in order to quantify the sodium intake intrinsically present in food. It consists by fifteen foods, and the frequency of consumption of each is reported by the patient. Other interviews used also assess behaviors related to salt intake (adding no more than 4g of salt in meals, avoid adding salt in food already prepared, as well as use of the salt shaker at the table, avoid the consumption of foods with high sodium levels) [21].

To answer the issues, present in these questionnaires / interviews researchers propose two types of scales, dichotomous and the Likert [4,13,19].

The origin of the dichotomous scale ("Yes = 0" or "no = 1") in relation to other forms of self-report, reside mainly in the construction of the questions in the negative, where the answer "No" means adherence [13], this fact allows to avoid the bias of positive responses [19]. The adherence level results from the simple addition of each item values [13], and only classifies the patient in adherent or non-adherent.

The Likert scale can vary in different possible answers ranging from never to always, considering that zero corresponds to never and the highest value, such as six matches ever [4]. The membership level is obtained by adding the values of each item and dividing by the number of items [13].

In both scales, higher values mean higher levels of adherence [13,19].

In order to analyze the data with a larger sample and test the sensitivity of the Likert scale to capture adherence patterns, we proceeded to the conversion of the Likert scale for dichotomous, which is known as "converted dichotomous scale". The conversion was made according to the following criteria: the Likert scale came to no. (1) of dichotomous scale, rarely (2) and (3) sometimes, often (4), almost often (5) and always (6), the Likert scale began to yes (0), the dichotomous scale [13]. Upon completion of the sum of the points and dividing by the total number of issues, it becomes a converted dichotomous scale this time to adherents and non-adherents [3].

In studies, there was an equal internal consistency for the Likert scale and when it is converted into dichotomous. Rather, the dichotomy scale has a low internal consistency. But within the Likert scale internal consistency also varies depending on the number of items, for studies with four items had lower internal consistency to the ones with seven items [13].

As for the standard deviation is more dispersing in the results in dichotomous scale than the Likert scale, especially the converted dichotomous scale, which has a very broad standard deviation, which favors starting its sensitivity to capture variations in treatment adherence [13].

### ***Registration of pharmaceuticals exemption in pharmacy***

It is being increasingly used and runs through computerized systems [1], as is the case in many Sifarma 2000 Portuguese community pharmacies [22]. In this method, the adhesion can be measured by the availability of medicine for multiple time intervals, the measuring intervals of multiple gaps in therapy, or for medicine possession rate [1]. This kind of method is associated with the medication electronic monitoring and the pills count [3,11].

### ***Medication Electronic Monitoring (MEMS)***

The most modern Method, expensive but accrued by Oigman [9], Mira and Filipa [10] requires the use of special flasks, containing a microprocessor in the cover, and it is based on the fact that each opening and closing of the cover to be stored as a dose [1,9]. The data collected later by a computer, inform the dates, times and the intervals between "probable" doses [9].

### ***Counting pills***

One of the most appropriate methods for this evaluation [9], is quite objective [11], quantifiable and easy to perform but does not provide information about interval between doses or about "free days without medication" [10]. It is associated often with other methods assessment of adherence to therapy [1]. For the calculation of the number of effective medicines taken during a certain time interval and the number of medicines prescribed, there is obtained the percentage of adhesion [13]. Values equal to or above 80% are considered compliant [9,13].

### **Discussion**

It is considered that non-adherence is a major cause of not controlled high blood pressure [19]. To measure the degree of

adherence of hypertensive patients to therapy direct and indirect methods were found [1].

Direct methods are objective but are very expensive and biological analysis does not assess how and when the patient made the doses which becomes a false impression of adherence [10].

Indirect processes as they require the patient's cooperation, and although they are the most used, from the outset, see their validity compromised, as these can hide or change information relevant to the evaluation.

This is very much present in the patient diary, for example elderly patients usually forget and confuse many past [9] events, and the psychometric measures.

Nevertheless, this type of self-reported methods, in contrast to techniques such as quantification of drugs and / or metabolites in body fluids, MEMS or pill counts are simple, rapid, non-invasive and economic [10], and can provide a look in real time about the adherent behavior and potential reasons for non-adherence of the patient [19].

A likely explanation for the increased use of questionnaires is the interest of health professionals in understanding the phenomenon of adherence / non-adherence which consequently leads to control/ no control of the PA [4].

Among the various questionnaires found, the method of Haynes and Sacket is the poorest in terms of information as it is constituted only by a single question [11].

But the questionnaire BMQ, the QAM-Q and the Hill-Bone scale cover three important areas that are directly related to the theme.

Initially, the use of the first scale of adherence to Morisky allowed to determine the adherent and non-adherent patients [4], as well as some of the causes [1]. With the creation of MMAS-8 began to be possible to measure the specific behavior of taking medicines, identifying aspects that are contributing or not to adherence [11]. But it was still not possible to evaluate the incorrect use of medicines [19], because it does not address issues such as time and method of use.

The MAT is composed of seven questions [3] in which the first four are adapted of Morisky. The other three items came uncover situations of non-compliance because they relate to situations that were not covered by the adherence of four items [13].

Overall, the approaches to adherence to antihypertensive treatment bring little emphasis on compliance verification instrument to dietary recommendations and physical activity [11]. Throughout this research there was a great difficulty in finding questionnaires to assess these two parameters that is to assess non-adherence. Just a self-report method was found, the scale of Hill-Bone, which relates to adhesion to medication and the consumption of sodium [18]. As described above, the non-compliance is not just the act of ingesting the medicine so there is the need for better evaluation of adherence, to create / crowd the various questionnaires, so that all the criteria can be evaluated.

Within the various types of scale that measure the level of compliance, the dichotomous only classifies the patient in adherent and non-adherent [13], as the other two mentioned have a higher sensitivity to rate the level of compliance, because a person can be adherent but not 100%.

The dispensing medication at the pharmacy registry method is not completely effective, since the patient can get their medication at another pharmacy and thus the calculations for the medicine possession rate or range of gaps in therapy are not true.

The collected data of the MEMS may indicate an overestimated adherence if the opening of the weak does not reflect the ingestion by the patient [9].

In pill counts even if the subjects had good adherence to treatment that does not mean he made use of the pills, as he may have removed the pills from blister / bottle without, however, ingest them and even that he has ingested them he may not have taken them in the right doses and times [1].

In short, evaluation methods of adherence to therapy currently available only provide an estimate of the current behavior of patient compliance [12].

## **Conclusion**

With this literature review, it is concluded that currently there is a method for evaluating adherence considered "gold standard" [1]. Although there are different tools that can be used to measure treatment adherence, direct and indirect methods, and some of them have a high sensitivity and specificity none has the ability to measure the level of adherence to therapeutic as a whole. It is necessary to evaluate the presence of factors that difficult the blood pressure control, such as excessive sodium intake, physical exercise and not taking medication or take it incorrectly [19]. It is therefore necessary that the search for the ideal method must be continued.

## **Conflict of Interest**

The authors confirm that this article content has no conflicts of interest.

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**\*Correspondence to:**

Isabel C. Pinto  
 Department of Diagnostic and Therapeutic Technologies  
 School of Health Sciences  
 Polytechnic Institute of Braganca  
 Av D. Afonso V, 5300-121  
 Braganca  
 Portugal  
 Tel: +351 273 330 981  
 E-mail: [isabel.pinto@ipb.pt](mailto:isabel.pinto@ipb.pt)