Review article

Methodologies for medication adherence evaluation: Focus on psoriasis topical treatment

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ABSTRACT

Adherence to topical treatment has been less studied in comparison with systemic therapeutic regimens and is poorly understood. High-quality research on this area is essential to outline a strategy to increase medication adherence and clinical outcomes. For a more comprehensive understanding of this issue, a systematic review of the methodologies for topical treatment adherence evaluation in psoriasis was undertaken. Twenty one studies were selected from the literature which used six different adherence methodologies. Merely three studies used multiple adherence measurement methods. The most used method was questionnaire (44%) which was also associated with higher variability of the adherence results. One possible explanation is the lack of a validated questionnaire designed specifically for the evaluation of adherence to topical treatment. Only one method (medication weight) takes into consideration the applied dose. However, the estimation of the expected weight is complex, which renders this method, as used presently, less effective. The use of a dosing device could improve its accuracy and be helpful to clearly instruct the patients about the correct dose. As there is no single method that allows an accurate and complete assessment of adherence it is recommended to use a combination of methods, including self-report and medicines' weight measurements.

Contents

1. Introduction

Adherence to medication can be defined as "the process by which patients take their medications as prescribed (. . .)" [1] and classified as primary or secondary [2,3] (Fig. 1). The evaluation of factors that influence treatment adherence remains one of the most important challenges in the management of any chronic skin

disease [4,5]. Medication adherence is crucial to achieve good clinical outcomes and high quality of patient care [6–10]. It is important to distinguish non-adherence from non-response and to analyse medication non-adherence before investigating possible pharmacologic reasons for non-response (drug failure) or starting alternative treatments. Besides, taking into consideration the high economic impact of non-adherence, adherence to the treatment promotes economic savings on the health care system [11]. Treatment adherence is scarcely discussed in the current dermatology literature. Topical treatment adherence has been less extensively studied than systemic treatment and is poorly understood [12–16]. In topical treatments, unique factors that influence adherence can be distinguished like the difficulty to specify the dose needed to cover the affected areas [17–20], the correct dose application [21] and the cosmetic acceptability of the medicines [22]. Topical treatment adherence evaluation is challenging and this complexity is reflected on the variability of adherence results reported in the literature for the same dermatosis [12,14]. For this purpose, an accurate and reliable methodology for adherence evaluation is needed [16,23,24]. The aim of this review was to document and compare the methodologies used for adherence evaluation in clinical research, focusing on adherence to topical treatment in psoriasis.

To our knowledge, the compilation and evaluation of the frequency of use of the methodologies for the assessment of adherence to psoriasis topical treatment, and the discussion of their influence on the adherence results is herein addressed for the first time.

The data collected will be useful to support the improvement of medication adherence studies which in turn are essential for the establishment of strategies to enhance adherence to treatment. Guidance for the development of novel pharmaceutical formulations can be also achieved.

1.1. Medication adherence evaluation

The different methods available for the evaluation of the medication adherence to topical treatment include the prescription record review, constant observation of the patients,

interviews, questionnaires, diaries, electronic monitoring devices and medication weight [25–27] (Table 1). The results obtained from the application of these different methods can differ substantially from each other and no single method can be considered suitable for all types of adherence research [27–30].

Adherence can be classified as primary and secondary being primary the redemption of a prescription and secondary the correct use of medication [2]. The prescription record review is a quantitative method to measure primary adherence that allows long term data recording in a large number of patients but requires existence of a complete electronic prescription database including validated variables for the calculation of adherence (e.g. number of days' supply of medication) [27]. Regarding secondary adherence, direct methods represent a proof that medication has been taken by the patient according to the treatment plan (dose and frequency), which for topical treatment is achieved by direct observation of the application of the medicine by the patient. Nevertheless, this method is impracticable in outpatients' settings [27]. Indirect methods for secondary adherence measurement can be categorized as patient self-reporting, clinical evaluation of patients by the dermatologist and medication measurement.

1.1.1. Patient self-reporting

Several methodologies for patient self-reporting have been used including interviews, questionnaires and diaries. Patient interview is an inexpensive and easy method however is only qualitative and influenced by question construction and interviewer's skill. Questionnaires are easy to administer (online, mail or phone) and can provide additional information about the reasons for non-adherence but accuracy is instrument-dependent. Diaries (paper and electronic) are quantitative records of regimen data (number of applications, schedules and omissions) that must be completed during medicine usage [26,27]. Electronic diary can enhance the features of this method since it provides a more effective data collection and can incorporate compliance-enhancing components (e.g. audible signals) [31]. Data interpretation regarding these methods must take into account the possibility of inaccurate filling of diaries. Usually patients over estimate
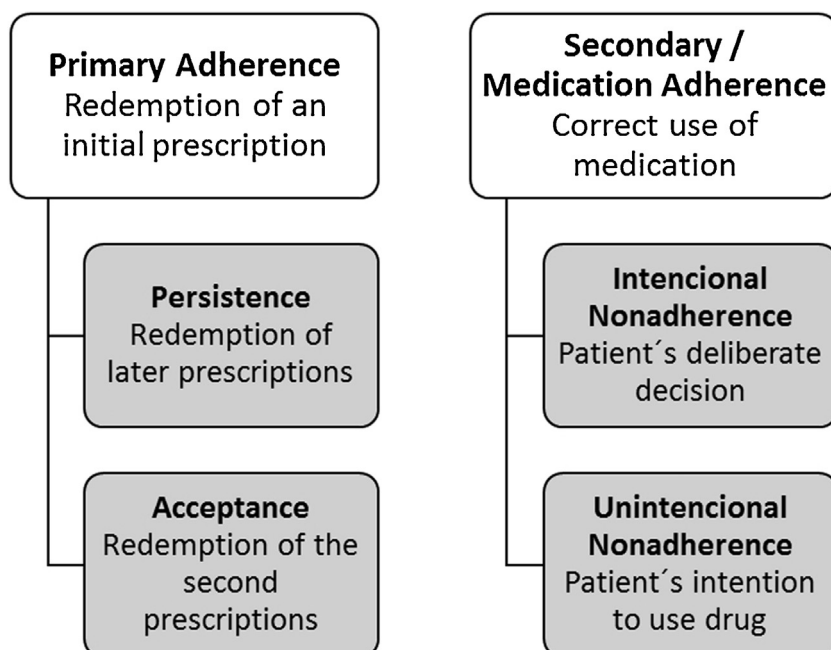

Fig. 1. Adherence Classification (Adapted from Storm et al. [2]).