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A study of adherence to antibiotic treatment in ambulatory respiratory infections

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SUMMARY

Objectives: To assess the different types of antibiotic-taking behavior and to compare self-reported with objectively measured adherence to antibiotic regimens in respiratory infections.
Methods: This was a prospective study of patients with suspected bacterial pharyngitis and lower respiratory tract infections recruited from five primary care clinics in Catalonia. Adherence to various antibiotic regimens was assessed by the Medication Event Monitoring System (MEMS), which recorded every opening of the patient's bottle of tablets, and a self-reported adherence question. The outcome variables were antibiotic-taking adherence, correct dosing, and timing adherence.
Results: A total of 428 patients were included in the analysis. Five types of antibiotic use behavior were observed: excellent adherence (130 patients, 30.4%), acceptable adherence over time (53; 12.4%), declining adherence over time (123; 28.7%), non-adherence to correct dosing (108; 25.2%), and unacceptable adherence (14; 3.3%). Excellent adherence was significantly associated with the number of daily doses of antibiotic and antibiotic duration. A total of 254 patients reported never forgetting to take the antibiotic (59.3%), achieving a negative predictive value of 100% and a positive predictive value of 51.2%.
Conclusions: Outpatients with respiratory infections treated with antibiotics showed poor adherence outcomes. Self-reported adherence was remarkably higher than that observed with the use of MEMS and failed to predict true patient adherence.
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1. Introduction

Medical adherence is defined as the extent to which a patient's taking of medication is consistent with medical or health advice.[1] Non-adherence to medications is particularly important in clinical practice. Adherence to medications has long been a concern because it often affects the outcome of treatment. In a review of 63 studies over a 30-year period, the authors reported that if the patient is adherent, the odds of a good outcome are almost three-fold higher than for those who are non-adherent.[2] In the case of infectious diseases, non-adherence to antibiotics might also lead to the storing of antibiotics at home, which induces self-medication, leading to a vicious circle, and thereby favoring the emergence of bacterial resistance.[3]

Measuring adherence is difficult because most of the direct and indirect measures available have limitations. Since their introduction in 1986, microelectronic devices have become the gold standard in adherence research.[4] The most commonly used system is the Medication Event Monitoring System (MEMS). MEMS medication bottles contain a microelectronic chip that registers the date and time of opening of every bottle. Assuming that the opening of a bottle represents the intake of medication, MEMS provides a detailed profile of the patient's adherence behavior. For this reason, MEMS is currently regarded as the gold standard for the measurement of adherence.[5–7] MEMS have been used to monitor adherence mainly with long-term medications, and in the case of infectious diseases, this technology has particularly been used to track medication adherence with antiretroviral agents and with anti-tuberculosis drugs. However, data on the antibiotic-taking behavior in respiratory tract infections in the community are lacking.[7] With the use of MEMS we previously observed that adherence to antibiotic regimens in respiratory infections decreased with an increase in the number of daily doses.[8]

Simple questions are the most commonly used measures of treatment adherence in medical consultation. The simplest question is asking if the patient has taken the treatment as requested. Physicians assume that patients provide honest answers and we usually believe their responses. However,

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self-reported questions may often provide inflated estimates of adherence behavior.[9] The use of a non-judgmental, non-threatening approach is therefore recommended, preceding the question with a remark such as the following: ''People often have difficulty taking their pills for one reason or another'', before asking if the patient has missed any dose.[10] The use of this approach decreases the overestimation of true adherence in chronic disorders, but the benefit of this in acute conditions such as respiratory tracts infections remains unanswered. In the current study we aimed to assess the different types of antibiotic use behavior among patients with respiratory tract infections and to compare the performance of a self-reported adherence question with objectively measured adherence of antibiotic regimens in these infections.

2. Methods

We performed a prospective, observational study in five general medicine outpatient clinics from 2003 to 2008 in Catalonia, Spain. We recruited patients aged 18 years or older presenting to the primary care practice with uncomplicated, acute (<7 days), suspected bacterial pharyngitis and lower respiratory tract infections. We excluded patients who had received previous treatment with antibiotics, those who presented criteria for hospitalization, those with any condition requiring the aid of other persons for drug administration, and those with hypersensitivity to antibiotics. The patients were treated with different antibiotic regimens previously included in the MEMS (Aardex Group Ltd, Zug, Switzerland) containers. The physicians decided which of these antibiotic treatments was to be administered.

Before the initiation of the study, the Spanish health authorities were informed about its characteristics and how it was to be conducted. Spanish legislation at the time of the study determined that institutional review board approval was not required for observational studies. However, the patients gave informed consent to participate in a study on the rational use of antibiotics. They were provided with complete information about the characteristics of the study and their participation, but were not informed at that time about the future assessment of adherence to avoid bias in the results. When they returned to the clinic, the physician collected the MEMS container and self-reported adherence was evaluated by means of the following question: ''We almost always forget to take all of the pills, did you ever forget to take any?'' Patients were fully informed about the results, and permission was requested to include these data anonymously in the current report. All the data included in the database were encoded to ensure confidentiality. The data contained in the microprocessors were transferred to the computer and processed with PowerView program v. 1.3.2. (Aardex Ltd). Multiple openings of the container within a period of less than 15 min were not counted.

2.1. Adherence parameters

Three different outcome measures were taken into account: (1) 'Taking adherence', calculated as the percentage of times the container was opened during the course of the treatment, related to the total number of pills included in the container. Good taking adherence was considered when it was greater than 80%. (2) 'Correct dosing', calculated as the number of days on which the patient opened the container at least the prescribed number of times, that is, at least three times for those assigned to the three times-daily antibiotics, twice for patients treated with twice-daily regimens, and once for those receiving once-daily antibiotic courses. For twice- and three times-daily regimens, dosing on day 1 may be restricted due to the late start of treatment (after visiting the physician), and this has to be taken into account. Good correct dosing was considered when it was greater than 80%. (3) 'Timing adherence', indicating whether the opening of the container coincided with the times recommended: intervals of 8+4 h during at least 80% of the three times-daily courses of antibiotics, 12+6 h intervals during at least 80% of the antibiotic course for the twice-daily antibiotics, and 24+12 h intervals during at least 80% of the antibiotic course for the once-daily antibiotics.

Excellent adherence was defined when these three adherence outcomes were good.

2.2. Statistical analysis

Descriptive statistics were used to describe the different adherence parameters observed in this study. We used Chi-square tests to compare proportions. The sensitivity, specificity, and positive and negative predictive values of the self-reported adherence question were determined with a two-way contingency table, using the adherence parameters provided by MEMS as the gold standard. A logistic regression model was constructed to identify variables significantly and independently associated with excellent adherence. The variables were included in the model if they were associated with a high score with a p-value of <0.10. Variables were eliminated from the model using the stepwise automatic variable screening method, the alpha thresholds for inclusion and exclusion being set at 0.20. Statistical significance was accepted at $p < 0.05$.

3. Results

A total of 481 patients were recruited. The self-reported adherence question was not registered for 37 patients. Furthermore, seven antibiotic treatment failures were observed requiring a change in antimicrobial treatment, and the adherence question was not evaluated in these cases. Seven patients did not return the MEMS container and two more refused to give consent (Figure 1). Of the 428 patients with complete information available for analysis, 236 (55.1%) received antibiotics three times daily, 151 received twice-daily antibiotic regimens, and the remaining 41 patients received once-daily antibiotic schedules. The different antibiotics used are described in Figure 1. A total of 251 patients (58.6%) were diagnosed with a lower respiratory tract infection and the remaining 177 patients were diagnosed with suspected bacterial pharyngitis. The mean age of all the patients was of 47.1 ± 21.2 years, and 231 were females (54.0%).

A total of 265 patients opened the vial at least 80% of the times (61.9%), 146 presented correct dosing adherence (34.1%), and 165 achieved good timing adherence for at least 80% of the antibiotic course (38.6%). Five patterns of antibiotic taking behavior were observed in this study: 130 patients (30.4%) achieved 80% of all the adherence outcomes and therefore presented excellent adherence. Another 53 patients (12.4%) missed only one dose for achieving excellent adherence and presented a relatively acceptable adherence during the antibiotic course. A total of 123 patients (28.7%) presented declining adherence over time with good correct dosing at the beginning of the antibiotic course followed by a reduction in the daily doses along the remainder of the course until the end. Thirteen of these patients (10.6%) abruptly stopped taking the tablets in the first half of the medication course. A total of 108 patients (25.2%) presented non-adherence to consistent correct dosing over time and 14 (3.3%) presented an unacceptable adherence pattern, with incorrect dosing and a further decline. The adherence parameters were consistently worse with three times-daily antibiotic regimens and better with once-daily courses ($p < 0.001$) (Table 1).

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