

Assessing compliance in asthma patients

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Compliance is usually defined as "the extent to which the patient's behaviour in terms of taking medications, following diets, or changing life style, coincides with the clinical prescription" [1]. This is a non-operative description which only refers to the patient, saying nothing about who gives and the quality of what is given, is often used to put the blame on the patient and to reassure the doctor.

The first step in assessing compliance should be an accepted definition of non-compliance, *i.e.* to define what is underdosing, overdosing, and more difficult, erratic dosing.

The second step in assessing compliance in asthma implies a correct diagnosis leading to an appropriate treatment, without any unnecessary prescription. Asthma treatment guidelines, defining what is considered efficient, have recently been published [2, 3]; it is likely to be fascinating to see how far doctors and patients will comply with these guidelines, and hence see their effectiveness.

What can we expect from compliance to an effective treatment? a) Reduced mortality: but even if these deaths are a reality and some perhaps avoidable, they are exceptional compared to the number of patients and practitioners. Furthermore, it is often said that those who die are those who are not compliant; but did they die because they did not take their drugs as non-compliant patients or did they die because there was something else causing non-compliance and, hence, their death? We also know that overcompliance, overreliance on medical prescriptions can kill patients. b) Reduced morbidity: but morbidity is the negative aspect of quality of life which is a very subjective judgment rooted in the person's valuation of health. What the patient feels, what he wants his life to look like and the benefit/cost ratio of compliance, vary from one to another depending on the preferences of each individual.

Actually, we do not know the relationship between compliance and the outcome of treatment; hence it is very difficult to measure the clinical benefit of improvement in compliance and to assess if improving compliance is not more harmful than good to those we try to convince.

Nevertheless, in practice, there are a lot of methods to assess compliance, each with its interests and limits: 1) medical judgment: usually unreliable; 2) appointments: but failure to keep appointments does not mean that the patient is non-compliant with the regimen; 3) patient's questioning, if confidence is there; it is the "less bad" method when used to find out the reasons of non-compliance; 4) puff, pill or tablet counts with electronic devices tabulating the actual time of usage, but not the

actual inhalation or swallowing; 5) measurement of concentrations of the drug or its metabolites in a body fluid, when possible, and if the individual pharmacokinetics of the patient are known. 6) diary, when the patient writes the truth [4]. 7) outcome, if there is no unnecessary prescription.

All these methods have been used in controlled clinical trials where compliance is a key-point, but even there the results obtained were far from those expected. Two examples: a) Compliance in "taking medications": many studies have shown the poor compliance of asthma patients with medications even under severe conditions [5], and the relationship between the daily prescribed dose frequency and compliance [6]; and these studies involve volunteers who are probably more compliant than those who decline to participate! b) Compliance in "executing life style changes": the difficulties we currently have to find a handful of patients to carry out studies on avoidance can only make us pessimistic about the actual achievement of this part of the prescription.

What is so difficult to measure in controlled trials can only be hypothesized in practice where prescriptions change from one country to another, from one region to another, from a medical school to another and from a practitioner to another. It is generally accepted that compliance is poor in asthma although, perhaps, not poorer than for other chronic diseases. A variety of explanations can account for this fact: asthma and its treatment combine all the characteristics which can keep a patient from being compliant. It is a chronic disease fluctuating from undetectable to death, the immediate, efficient drugs are often symptomatic and inefficient in the long run, and those drugs which are efficient in the long run are often inefficient on the immediate symptoms. But does it matter? Is compliance really compulsory in asthma? Is our stubborn quest for compliance really worth it, and if so, when do we *have* to assess compliance in practice, apart from clinical trials where everything must be done to assess the efficacy of a drug or a procedure? The answers to these questions are not so easy to find out: 1) when a treatment is inefficient, because it would be ridiculous to try to fine-tune a treatment which would not be taken; 2) when there are side-effects, to make sure that the drugs prescribed are causal, especially when the accused drugs are the cornerstone of the treatment. Unfortunately, experience shows that even if we have a clear demonstration of the safety of the drug, confidence has melted away, and the patients no longer comply; 3) but do we have to assess compliance when a treatment looks efficient and is devoid of side-effects, even if it is a "pseudosuccess"?

Asthma is a chronic, usually mild and fluctuant disease lasting for years with no danger for people around the patient. Therefore, the decision of complying or not

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belongs to him; and he has seen so many prescribing fads come and go! So to assess compliance in asthma, as a general concept, does not seem so important after making sure that the patient's non-compliance is not related to another individually or socially solvable problem. We could also assess the principle of compliance in asthma. Compliance is a behaviour, the result of a complex association of attitudes and beliefs about the disease, drugs and medicine; it is closely related to the patient's personality. To improve compliance means to improve the patient's submission to the regimen when he might expect from his doctor, who acts on his behalf, a guidance on his autonomy, his freedom to choose between different possibilities, perhaps an intelligent non-compliance.

The patient needs help and understanding; he owns his body and destiny and, ultimately, is the best judge of his own interests, provided that he is properly informed, and remains the final master of the treatment decision and implementation. Compliance is a narrow path leading from efficacy to effectiveness; we have to make it easy and attractive to the patient-trekker who will choose it...may be.

References

1. Haynes RB. – Determinants of compliance: the disease and the mechanisms of treatment. *In*: R.B. Haynes, D.W. Taylor, D.L. Sackett eds, *Compliance in health care*. Baltimore: John Hopkins, 1979.
2. British Thoracic Society. – Guidelines for management of asthma in adults: I-chronic persistent asthma. *Br Med J*, 1990, 301, 651–65.
3. British Thoracic Society. – Guidelines for management of asthma in adults: II-acute severe asthma. *Br Med J*, 1990, 301, 797–800.
4. Spector SL, Kinsman R, Mawhinney H, Siegel SC, Rachelefsky GS, Katz RM, Rohr AS. – Compliance of patients with asthma with an experimental aerosolized medication: Implications for controlled clinical trials. *J Allergy Clin Immunol*, 1986, 77, 65–70.
5. Chryssantopoulos C, Laufer P, Torphy DE. – Assessment of acute asthma in the emergency room: Evaluation of compliance and combined drug therapy. *J Asthma*, 1983, 20, 35–38.
6. Eisen SA, Miller DK, Woodward RS, Spitznagel E, Przybeck TR. – The effect of prescribed daily dose frequency on patient medication compliance. *Arch Intern Med*, 1990, 150, 1881–1884.

The assessment of therapeutic compliance by asthmatic patients

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The assessment of patient compliance with prescribed therapeutic regimens is notoriously difficult. The problems are greater when considering the treatment of asthmatic subjects due to the prominence of the inhaled route for the delivery of drugs. The methods employed fall broadly into two categories; those which are indirect, assessing only what drug may have been taken and, secondly, those which directly measure the presence of a drug, or associated marker substance, in a biological fluid. Neither are entirely satisfactory and ideally a combination of both should be employed.

The simplest indirect method is to ask the patient what drugs he has taken and how often. This can be on a simple retrospective basis or undertaken prospectively using diary record sheets. Although having the considerable advantages of being universally applicable and both simple and cheap, this method suffers from being the most inaccurate of any available. In general, patients are thought to over-estimate their actual drug use by between 30 and 50% [1]. ZORA *et al.* [2] have reported that only one of seventeen diary sheets completed by asthmatic children was accurate to within 10 percent of the number of puffs used as calculated by inhaler weights.

Even when patients are aware that their statements will be verified by more objective measurements, they cannot

be relied upon to give entirely truthful responses. Thus ZUCKERMAN *et al.* [3] found cannabinoid metabolites in the urine of 35% of pregnant adolescents who had denied using cocaine, despite being informed that urine assays would be performed. Although this may not seem relevant to the use of more immediately legitimate drugs, it is in keeping with most other studies such as that reported by the author in which 11% of asthmatic patients who claimed to have inhaled salbutamol in the preceding four hours had no detectable drug in their urine. Patient questionnaires have generally been held only to result in deliberate over-reporting of drug use. However there is clear evidence that many patients deliberately report much smaller drug intakes than they have actually used - for example almost one in five patients seen in general practice had urine salbutamol concentrations much higher than predicted from their reported intake [4]. It has been suggested that patients who admit to poor compliance may be more amenable to compliance modifying strategies. Although to date there has been no prospective validation of this hypothesis it does further ensure that the patient questionnaire will remain as a central plank of compliance assessment strategies.

Regrettably the physician can give no more an accurate picture of his patient's compliance. CARON and co-workers [5] have shown that physicians of all levels of experience cannot predict which patients will follow their prescribed drug regimen. Use of records