Original article

Patient non-compliance with drug regimens for chronic diseases in northwest Ethiopia

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Abstract

Background: Poor compliance with prescribed medication is a major problem in chronic disease states and is often responsible for the therapeutic failure. It also unnecessarily increases the costs of health care.

Objective: To assess the magnitude and factors of non-compliance with medication prescribed for chronic diseases (tuberculosis, diabetes, epilepsy, asthma, hypertension, congestive heart failure and other cardiovascular diseases).

Methods: A community based cross-sectional study was conducted in Gondar town and Dabat Wereda, Northwest Ethiopia between March - June 2000. A random sample of 600 patients was included in the study. An indirect method (patient interview) was employed.

Results: The overall incidence of non-compliance was 42%. The study identifies reasons why patients don't comply with drug treatments. Almost two-third of the cohort either lack money to buy drugs or feel the side effects of drugs to be intolerable or forget to take them.

Conclusion: Non-compliance has been established to be a major detractor from the provision of optimal therapy. Greater emphasis should be placed on intervention strategies, such as patient counselling, distribution of essential drugs to all health care units, and increasing the awareness of health professionals about the issue of non-compliance. [*Ethiop. J. Health Dev.* 2001;15(3):185-192]

Introduction

Medication compliance has been defined in terms of an agreement between the patient's behavior of taking medications and the clinical prescription (1). Faulty compliance or non-compliance with medications may include errors of purpose, timing or dosage as well as total or partial omission, or use of inadvertent combinations. Non-compliance with medications is one of the major factors in the failure of therapeutic programs in patients having a chronic disease (1).

In the available literature, the magnitude of non-compliance with medications prescribed for patients with chronic illnesses such as tuberculosis, hypertension, asthma, diabetes, epilepsy and congestive heart failure ranges between 16.7% and 80% (2-11). Another study conducted on epileptic and asthmatic patients showed an overall incidence of non-compliance with phenytoin and theophylline therapy to be as high as 63% (12).

Generally, the compliance of patients decreases with time and it is lower in long-term medications than in short-term medications. In depressive patients, compliance was shown to be 68% after 3 weeks of treatment, but this percentage decreased after 6, 9 and 12 weeks to 63%, 50% and 40% respectively (13). A compliance study conducted with short-term medications revealed an overall incidence of non-compliance of 26% (14).

It is true that the possible factors of non-compliance may vary form country to country and may contribute to the variations that exist

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among the reported values of non-compliance. With regard to the possible factors of non-compliance that are related to the patient, the disease, the drugs prescribed, the physician and the treatment environment (15, 16), the magnitude of non-compliance is expected to be high in Ethiopia. Nevertheless, few studies are conducted to address such an important public health issue in Ethiopia, particularly in north-west Ethiopia.

Therefore, the main objective of this study was to assess the magnitude and factors of non-compliance with therapeutic regimens prescribed for the treatment of chronic diseases such as tuberculosis, diabetes, asthma, hypertension, congestive heart failure, epilepsy, angina pectoris and chronic rheumatoid valvular heart disease.

The results of the study may contribute to increase the awareness of health care providers particularly physicians on the issue of compliance and may aid to develop strategies for improvement of compliance.

Subjects and methods

A community based cross-sectional survey was conducted between March - June 2000 in Gondar town and Dabat Woreda. The subjects of the study were outpatients with chronic illnesses who attended the specialized chronic illness centers at Gondar hospital, Gondar polyclinic and Dabat health center. The selected patients from Gondar were urban dwellers whereas those of the Dabat Woreda were rural dwellers.

The assumptions for sample size determination were a 50% prevalence of non-compliance (as no previous data is available), a 95% confidence level with a deviation of $\pm 4\%$ from the true prevalence. Based on the above assumptions the calculated sample size was 600. Then the obtained sample size was distributed among the residence of patients (Gondar and Dabat) and disease type (tuberculosis, diabetes, epilepsy, hypertension, asthma, congestive heart failure, other CV diseases) proportionally. Other cardiovascular (CV) diseases include angina pectoris, paroxysmal supra ventricular tachycardia (PSVT) and chronic rheumatoid valvular heart disease (CRVHD). The selected patients were those who were expected to be on medication during the study period according to their medical records.

A structured questionnaire consisting of both open-and closed ended questions was prepared and piloted to evaluate the feasibility of conducting the study. Patient and drug related information were obtained from the chronic illness centers and filled on the questionnaire. Trained data collectors (nurses) visited the patients at their homes and interviewed them or their caretakers after obtaining an informed consent. Patients were not informed about the date of the visit nor its purpose previously to avoid bias. Subjective method (face-to-face interview) was employed in order to obtain information about: Socio-demographic variables, treatment regimen, and general questions related to the use of drugs. Finally data were entered into the computer and analyzed using EPI-Info Version 6.02 statistical package.

The operational definition of *Compliance* in this study was a 100% adherence to a clinical prescription, which was more conservative than the definition of *defaulting* (as used for TB patients). Accordingly, missing even a single dose out of more than one prescribed doses was considered as a non-compliant behavior.

Results

From a total of 600 patients with identifiable home addresses, 540 patients were found at their addresses and responded for the interview, which gives a 90% response rate. From the remaining 60 non-respondents, 42 were reported to have died and 18 could not be reached at the time of repeated home visits made.

The mean ($\pm$ SD) age of the patients was 36.8 $\pm$ 17.2 with a male/female ration of 0.9:1.0 (Table 1). The drugs prescribed for the

Table 1: **Age and Sex distribution of patients with chronic illnesses (n=540), Gondar town and Dabat Woreda, 2000**

Characteristic	Number	Percent
Age		
< 5	10	1.8
4 - 14	26	4.8
15 - 49	372	68.9
50 - 64	97	18.0
65+	35	6.5
Sex		
Female	284	52.6
Male	256	47.4

Patients with chronic diseases are presented on Table 2. The number and type of drugs prescribed for chronic diseases other than tuberculosis were more or less similar both in Gondar and Dabat Woreda. Directly observed treatment strategy (DOTS) program was used in Gondar for treatment of tuberculosis whereas this was not the case in Dabat Woreda (here rifampicin, pyrazinamide and vitamin B_6 were used infre-quently).

The overall noncompliance rate of the patients with chronic illnesses in this study was 42% (Table3). The non-compliance rate in asthmatic and tuberculosis patients was higher than the overall non-compliance rate. The compliance of patient with chronic rheumatoid valvular heart disease was the highest (100%).

Table 2: **List of drugs prescribed for the study subjects, Gondar and Dabat, 2000**

Type of disease	Drug prescribed	Remark
Tuberculosis	Isoniazid	Used in all patients
	Pyrazinamide	Less used in Dabat
	Rifampicin	Less used in Dabat
	Ethambutol	Frequently used in Dabat
	Streptomycin	Used in Dabat
	TB450	Used in Dabat
	Vit B_6	Rare use in Dabat
Diabetes	Lente insulin	
	Glibenclamide	
Epilepsy	Phenobarbitone	
Hypertension	Alpha methyldopa	
	Hydrochlorothiazide	
Congestive heart failure	Digoxin	
	Fursemide	
	KCl	
Asthma	Theophedrine	
	Prednisolone	Rarely used
	Albuterol	
Others	Benzathine-penicillin	For CRVHD
	Propranolol	For PSVT
	Nitroglycerin	For Angina Pectoris

Table 3: **Compliance status of patients with chronic illnesses (n=540), Gondar and Dabat, 2000**

Type of illness	Non-complaints Number (%)	Complaints Number (%)	Total
Asthma	41 (69.5)	18 (30.5)	59
Tuberculosis	63 (49.2)	65 (50.8)	128
Hypertension	36 (42.9)	48 (57.1)	84
Congestive heart failure	14 (36.8)	24 (63.2)	38
Diabetes Mellitus	39 (34.2)	75 (65.8)	114
Epilepsy	28 (29.2)	68 (70.8)	96
Other CV diseases	6 (28.6)	15 (71.4)	21
Total	227 (42.0)	313 (58.0)	540

The factors of non-compliance are shown in table 4. Most of the patients mentioned only one factor for not complying to a clinical prescription. Lack of money, the occurrence of side effects and forgetfulness account for almost two third of the total factors of non-compliance. Lack of money was frequently mentioned by tuberculosis and diabetic patients who were not able to buy particularly rifampicin and lente insulin. Side effects of drugs, particularly antiasthma drugs and anti TB drugs rank 2nd among factors of non-compliance. Side effects such as gastritis were frequently mentioned by asthmatic patients taking the ophedrine; yellowish-red urine discoloration, psychotic symptoms, visual disturbances, were mentioned by tuberculosis patients.

Table 4: **Factors of non-compliance (n=239), Gondar and Dabat, 2000**

Factor	Frequency		Remark
	Number	Percent	
Lack of money	54	22.6	Mainly TB & diabetic patients
Side effects	52	21.8	Mainly Asthmatic and TB patients
Forgetfulness	46	19.3	More common in urban patients
Distance	26	10.9	More common in rural patients
Improvement of the disease	24	10.0	Mainly in epileptic & hypertensive
Unavailability of drugs	18	7.5	Antidiabetic and cardiovascular drugs
Misunderstanding of instructions	9	3.8	Rural patients
Shift to herbal medicines	8	3.3	Asthmatic patients
Imprisonment	2	0.8	
Total	239	100	

Table 5 shows the responses of the subjects of the study to some general questions related to pharmacotherapy according to their subjective assessment. With regard to the outcome of therapy, 94.3% of the complaints reported to benefit from the prescribed drug(s) whereas a similar outcome of therapy has been reported by 85% of the non-complaints. There was a statistical significant difference in the outcome of therapy between the compliant and non-compliant groups ($\chi^2=12.87$, $P<0.01$). When asked whether they have visited modern health institution as they first experienced the signs and symptoms of the disease, 68.5% of the patients responded with yes answer whereas the remaining 31.5% of the patients reported to have used other approaches such as traditional medicines, holy water or even in some cases consulting wizard. The provision of drug related information by prescribers and drug dispensers was 97% and 92.2%, respectively. Drug sharing with other persons was reported by 7.4% of the patients (most of them, asthmatic patients). A considerable percentage of patients reported to use particularly holy water (as a bath or drink) in addition to the prescribed therapeutic regimen.

Table 5: **Information related to pharmacotherapy (n=540), Gondar and Dabat, 2000**

Parameter	Yes		No	
	Number	Percent	Number	Percent
Perceived benefit of pharmacotherapy*:				
Complaints (n=313)	295	94.3	18	5.7
Non-complaints (n=227)	193	85.0	34	15.0
Timely visit to health institution	370	68.0	170	31.5
Provision of drug-related instruction by prescribers	524	97.0	16	3.0
Provision of drug-related instruction by dispensers	498	92.2	42	7.8
Drug sharing with other persons	40	7.4	500	92.6

*$\chi^2=12.87$, $P<0.01$

Discussion

According to the operational definition of this study, the overall level of non-compliance was found to be 42%. This underlines the seriousness of non-compliance as a problem in the provision of health care. It is probable that the degree of non-compliance might have been underestimated as the subjective method (patient interview) employed for an assessment of compliance usually underestimates non-compliance (17).

When individual chronic illnesses are seen separately, the incidence of non-compliance to antiasthma (69.5%) and anti TB drugs (49.2%) was higher than the overall incidence. The same definition of compliance was employed for all types of chronic diseases in order to maintain uniformity in the technical interpretation of the results. The definition refers mainly to the adherence of patients to the physician's instructions rather than the outcome of therapy. Therefore, it may be difficult to make a straightforward comparison of the compliance results among the different chronic diseases. The occurrence of side effects particularly with antiasthma and antituberculosis medications, a high cost of some antituberculosis drugs (e.g. rifampicin) as well as an increased number of drugs to be administered might have attributed to such a high rate of non-compliance with antiasthma and antituberculosis medications. Expectedly, the least non-compliance degree (0%) was found in patients with chronic rheumatoid valvular heart disease where the drug is administered less

frequently (once monthly) and passive co-operation of the patients is required. It has been reported that increased number of drugs and more frequent administrations of particularly oral medications are associated with higher non-compliance degrees (13, 18).

The incidence of non-compliance with some reported therapeutic regimens is as follows: Theophylline, antiasthma drug, 39% (5) to 70% (10); Rifampicin and other anti-TB drugs, 16.8% (3) to 80% (11); Chlorpropamide and metformin oral hypoglycaemics, 65% (9); Digoxin, used in congestive heart failure, 40% (6); Hypotensive drugs, 16.7% (2). In another compliance study conducted on 80 epileptic and asthmatic patients, an overall incidence of non-compliance of 63% has been reported (12).

The variations that exist among the literature values and that of our study may partly be explained by the differences in the methods employed and definitions of compliance and therefore, straightforward comparison and interpretation of the results may be difficult. A non-compliance degree of 42% (the present study) is however within the range of the literature values. The fact that the subjects of the present study regularly visit the specialized chronic diseases' centers and get instructions from their physicians might have contributed for the compliance of patients.

Non-compliant behavior is dependent upon several interacting variables that are related to patient, the patient's illness, the physician, the drugs prescribed, and the treatment environment (15, 16). The investigated factors of non-compliance in this study are of one or more of the above-mentioned origins. Some important drugs such as anti-diabetic and anti-TB drugs were not redeemed by some patients of this study, which was mainly due to lack of money. Non-redemption of the prescribed medications has also been reported in previous studies (14, 19). The maintenance of an adequate stock of essential drugs at a reasonable cost in all public health care units and the provision of free health services for the extremely poor patients and for those diseases with long treatment duration need be given special attention. The discontinuation of the treatment regimen due to side effects of drugs, the feeling of an improvement of the disease, preference to traditional medicine etc., could at least be minimized by adequate patient-physician interaction. The importance of an adequate patient-physician interaction as one of the strategies in improving compliance has been pointed out in many literature (14, 16, 20, 21, 22). The quality, duration and frequency of interaction between the patient and the physician may be variable. The provision of drug-related instructions to the patients by prescribers was high (97%) in this study possibly because of the specialty of the treatment environment. A detailed explanation about the nature of the disease and the drugs prescribed would increase the participation of the patients in the treatment program. The prescription of isoniazid without Vit B_6 (as seen in Dabat) increases the likelihood of isoniazid-induced side effects and is likely to provoke non-compliance.

The factors of non-compliance, which are identified in the study, lead to under use of drugs that may prevent patient from obtaining optimal therapeutic benefit from the prescribed regimen. This in turn may prevent the health care providers particularly physicians from effectively evaluating the efficacy of the regimen and misguides them to shift to other alternatives (20). The other alternatives to be prescribed can be more expensive, less effective or even more toxic with serious socio-economic and therapeutic implications. The matter can be more complicated if the problem of compliance leads to the development of resistance to prescribed first-line drugs as in the case of tuberculosis. The fact that a significant percentage of compliant versus non-compliant patients have reported beneficial effects of the treatment regimens, interventional strategies are required to improve the compliance of patients with long-term medications.

In conclusion, since non-compliance has been established to be a major detractor from the provision of optimal therapy, greater emphasis should be placed on intervention strategies, such as patient counselling, distribution of essential drugs to all health care units, and increasing the awareness of health professionals and students about the issue of non-compliance. It should also be mentioned that non-compliance can adversely affect the drug budget of the country and wastes the precious time of the physician. Further research into this problem and its possible solutions could be highly beneficial for patient with chronic illnesses.

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