

Non-compliance in a large population of elderly patients with cardiovascular disease

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ABSTRACT

Background: Non-compliance with prescribed drugs is an important cause of hospitalization in elderly patients due to multiple psychological and physical barriers, multiple diseases and the use of a wide variety of drugs. We aimed to examine the causes of non-compliance and the contribution of non-compliance in hospital admission among elderly patients with cardiovascular (CDV) diseases.

Methods: A retrospective study of 922 patients aged ≥ 65 years admitted during the period Jan. 2004 – Jan. 2006 in the Geriatric Department of "Dr. C.I. Parhon Hospital" for CDV diseases was conducted. Data on compliance was collected through a questionnaire on compliance, beliefs, knowledge, and self-care behavior and compared with information from past medical records or from family members. We assessed the main causes of hospital referral, carefully looking for possible or probable cases of non-compliance. The main causes of non-compliance were also assessed.

Results: The mean age of the study group was 74.5 years (65-91), M:F ratio was 42:58,9% were living alone and 59% completed high school. The average number of different drugs prescribed was 4.3 and the average number of pills taken daily was 5,8. Ninety patients (9,76%) were hospitalized for aggravation of their CDV disease due exclusively to non-compliance and 148 (16,05%) had other factors that led to non-compliance (e.g. nausea and vomiting, dizziness, negative stress).

The non-compliant population ($n = 90$ patients) lived equally in urban and rural area. Most of them were 70 to 80 years old (48,89%), did not complete high school (72,22%) and had a very low income. The rate of hospitalization in these patients in the study period was 1.84 /patient. All the patients had heart failure (HF) due mainly to ischemic heart disease (46,67%) followed by hypertension (18,89%), arrhythmias (17,77%) and dilatative cardiomyopathy (16,67%).

The main self-reported causes of drug non-compliance were inadequate income (34,2%), inadequate instruction (17,7%), too many drugs (17,7%) and physical barriers (visual disturbances or arthritis) (11,11%).

Conclusions: Our study helps identifying several characteristics of aged patients with CVD at risk of non-compliance. The most important causes for non-compliance were inadequate income to fill the prescription followed by inadequate instruction combined with an increased number of pills (> 3 pills/d).

Keywords: non-compliance, therapeutic efficacy, hospitalization

INTRODUCTION

According to the *Encyclopedia of Biopharmaceutical Statistics* compliance is defined as: a) The act of complying with a wish, request, or demand. b) Willingness to follow

a prescribed course of treatment (medical) (1). Compliance is a complex behavioral process strongly influenced by the environments in which patients live and healthcare providers practice. Furthermore, non-compliance represents the

extent to which the patient's behavior does not follow medical recommendations.

Non-compliance is an old phenomenon. The first recorded case took place in the Garden of Eden with dire consequences. However scientific interest on non-compliance started in 1943, but it was only 20 years ago when the seriousness of the problem was fully recognized and research began (2). Recent studies (3,4,5) report that up to 60% of all medication prescribed is taken incorrectly, or not at all.

Although the term non-compliance encompasses a wide range of patients, it was noted that the elderly are particularly vulnerable. 90% of elderly patients make some medication errors, and 35% make potentially serious errors. Some of the reasons why the elderly may have trouble taking their medication correctly and on time are related to:

- physical barriers: weakness, arthritis, tremors; wheelchair or bedridden patients may have difficulty getting up several times a day to take their medication;
- functional barriers, such as memory loss (they simply forget to take their medication on time), confusion (it occurs especially with multiple drugs and complex regimens), insufficient income, multiple pharmacies, solitude (6).

Physicians are unable to predict patients' non-compliance at rates better than chance. When a medical professional asks about compliance, patients tend to exaggerate ("white coat" effects). Therefore, patients' self-reports usually overestimate compliance by a significant amount (7).

Non-compliance increases healthcare costs. Of note some extremely relevant but largely unknown facts:

- about 225 million hazardous situations are created each year by non-compliance in the world (8);
- an estimated 125,000 lives could be saved annually with better compliance based on heart disease only (9);
- non-compliance is directly responsible for the admission of 380,000 patients to nursing homes each year, which means 23% of all nursing home admissions (16). In 60% of all nursing home admissions, non-compliance has a more important impact than the person's actual medical condition (10);
- non-compliance leads to 3,5 million hospital admissions annually in the United States, or 11% of all admissions (11);
- in elderly, 40% of all admissions are due to medication-related problems (2). The mean cost per admission in these cases has been estimated at \$2,150 (12);
- non-compliance is the most important single cause for readmission to hospital (12);
- the total price of non-compliance is \$100 billion annually in the United States (10).

Our study tries to identify for the first time in Romania the contributing factors that may affect the therapeutical compliance in the elderly leading to hospitalization. □

METHODS

A retrospective study of 922 consecutive patients aged ≥ 65 years admitted for CDV disease during Jan. 2004 – Jan. 2006 in the Geriatric Department of "Dr. C.I. Parhon Hospital" was conducted. Data was collected for each person by way of a questionnaire on compliance, beliefs, knowledge, and self-care behavior. Medical records were used to obtain diagnosis at admission, drug history, and to corroborate information provided by patients during the interview. Patients were asked to explain their medication; this was compared with information from past medical records or family members. At readmission, non-compliance was specially assessed as a cause for re-hospitalization.

Causality between non-compliance and hospitalization was further noted based on the following definitions, according to Schechtman:

- definite or probable causality:
 - a) a clear temporal association between non-compliance and onset of symptoms,
 - b) signs and symptoms were improved by readjustment of treatment, and
 - c) the signs and symptoms could not reasonably be explained otherwise;
- possible: other possible causes could explain signs and symptoms of the patient.

ASPSS 11.0 was used for all statistical calculations. Results were expressed as mean values \pm SD. Differences between groups were assessed by ANOVA and t-test. For non-parametrical distributions the chi square test was used. A $p < 0,05$ was considered significant. □

RESULTS

From the analysis of interviews three groups were derived: Group I (N = 90) (9,76%) – patients hospitalized for aggravation of their cardiovascular disease due only to non-compliance (definite causality), Group II (N = 148) (16,05%) – patients hospitalized for aggravation of their cardiovascular disease due to other factors that subsequently caused non-

	Group I (N = 90)	Group II (N = 148)	Group III (N = 684)
Mean age, years	73,5 [65-91]	74,5 [65-91]	75,5 [65-91]
Gender (% M)	51 (56,7%)	79 (53,4%)	400 (58,5%)
Living alone, %	14,4%*	6%	7,2%
Living area (% rural)	50 (55,5%)	80 (54,1%)	367 (53,6%)
Completed high school	25 (27,78%)*	62 (41,89%)	357 (52,19%)
Monthly income			
• < 100 Euro	65 (72,22%)*	85 (57,43%)	367 (53,65%)
• > 100 Euro	25 (27,78%)*	63 (42,56%)	317(46,35%)
Average number of different drugs prescribed	4.7 ± 0,11	3.9 ± 0,20	4 ± 0,13
Average number of pills taken per day	6.2 ± 0,09	5.7 ± 0,10	5,5 ± 0,11
Mean hospitalization, days	8.5 ± 0,23	6.5 ± 0,14	6 ± 0,18
Mean cost hospitalization/day (Euro)	323 ± 2,46	303 ± 3,04	304 ± 2,78
Total cost hospitalization (Euro)	2745,5 ± 34,88*	1969,5 ± 26,70	1824 ± 32,45
Main cardiovascular disease			
• ischemic heart disease	42 (46,67%)	62 (41,89%)	303 (44,30%)
• hypertension	17 (18,89%)	38 (25,68%)	178 (26,02%)
• arrhythmias	16 (17,77%)	36 (24,32%)	185 (27,05%)
• dilatative cardiomyopathy	15 (16,67%)**	12 (8,11%)	18 (2,63%)
Cardiovascular risk factors			
• smoking	35 (38,88%)*	30 (20,27%)	122 (17,84%)
• alcohol	30 (33,33%)*	25 (16,89%)	116 (16,96%)
• obesity	14 (15,55%)*	43 (29,05%)	197 (28,80%)
• high level of cholesterol	45 (50%)*	38 (25,68%)	164 (23,98%)
• diabetes	16 (17,77%)**	41 (27,70%)	205 (29,97%)

TABLE 1. Characteristics of the three groups; the results are expressed as mean values ± SD

* = p < 0,01 group 1 vs group 2 and 3

** = p < 0.01 group 1 vs group 3

compliance (possible causality) and Group III (N = 684) (74,19%) – patients hospitalized for heart failure due to cardiovascular aggravating factors (no causality).

Characteristics of the three groups are presented in Table 1.

There were no significant differences between the three groups concerning mean age, male/female ratio and living area (urban/rural). There was a major preponderance of patients living alone, with a lower education and a lower income (< 100 Euro) in Group I. There were no differences between the three groups concerning the average number of different medications prescribed, the average number of pills taken per day, the mean number of days of hospitalization, the mean cost of hospitalization per day (Euro). The total cost of hospitalization per patient (Euro) (2745,5 vs. 1969,5 and 1824 respectively) was significantly higher in Group I.

All the patients from Group I were admitted for HF due mainly to ischemic heart disease and hypertensive encephalopathy. Other causes such as recent onset of atrial fibrillation and unstable angina were in a significantly lower

number in the non-compliant group compared with the other two.

The analysis of cardiovascular risk factors revealed that smoking, excessive alcohol intake and high levels of cholesterol were significantly increased in the non-compliant group which suggests that patients who smoke and/or consume alcohol in excess should be followed up more carefully for noncompliance. Obesity and diabetes were significantly increased in the other two groups.

The most common causes of non-compliance among elderly patients (Table 2) were

Causes	Number of patients
Inadequate income	30 (34,2)
Inadequate instruction	16 (17,7)
Too many drugs	16 (17,7)
Physical barriers	10 (11,11)
Unpleasant side effects from the medication	5 (5,55)
Depression, loneliness	5 (5,55)
Perceived as not necessary	5 (5,55)
Deliberate under-dosing	5 (5,55)

TABLE 2. The main causes of non-compliance

inadequate income followed by inadequate instruction, both medical (the patient had not understood the importance of filling the prescription or taking the medication or respecting the diet) and personal (the patient could not read the labels or the timetable of the medication). Sixteen patients considered that they have to take too many drugs so they stopped taking them altogether, 10 patients had physical barriers (visual disturbances or arthritis which enabled them to take medication properly), 5 patients had unpleasant side-effects from the medication (3 had swollen ankles due to Nifedipine and 2 had headaches due to nitrates), 5 patients were living alone and experienced depression; furthermore, 5 patients perceived treatment as not necessary and 5 patients under-dosed medication deliberately. □

DISCUSSION

Poor compliance to prescribed medication is a common problem that can have a major impact on the success of routine patient care and on the conduct and conclusions of clinical trials, especially in elderly patients. The potential effects of inadequate compliance in clinical trials include underestimation of the true therapeutic efficacy (medication is not taken as intended) and large increases in sample-size requirements. If the therapeutic impact of poor compliance is of sufficient magnitude, the associated reduction in statistical power can lead to negative conclusions in a study that might otherwise have been positive (13). Poor compliance may take many forms, e.g., not following dietary or exercise recommendations, not taking the prescribed number of pills or taking them at irregular or otherwise nontherapeutic intervals, not refilling prescriptions, and not showing up at follow-up clinic visits (8).

We focused on compliance to medication regimens in a population of elderly patients with CVD. Our data demonstrate that from a total number of 922 patients only 9,76% were hospitalized due exclusively to non-compliance while 16,05% were hospitalized due to non-compliance associated with other factors such as concurrent illnesses that had alarming symptoms: chronic respiratory disorders, depression, constipation, diarrhea, nausea and vomiting, arthritis. However, we believe that the real number of cases of non-compliance might be higher as patients tend to underreport their non-compliance.

Our findings are comparable with previous reports (14,15,16,17,18), even though other studies included all age groups and used different definitions for non-compliance. Campbell (14) considers that for reaching current targets recommended by guidelines, most patients will require up to four drugs to control their high blood pressure, with many also taking aspirin and a statin, which will lead to five or six drugs per day. Benefits from adding a fifth or a sixth drug are small and have an equal or greater chance of side effects and interactions. People older than 60 (the majority of patients with hypertension in general practice) and people with diabetes are less likely to comply with medical recommendations. Cohen (15) considers that compliance problems are common causes of the inadequate treatment of hypertension, with 16% to 50% of patients quitting treatment within one year.

Non-compliance is associated with an important financial burden. The mean duration of hospitalization was 7 days and the mean cost per day was 323 Euro, which means that the average cost of non-compliance cases per patient was about 2745,5 Euro. The 90 patients hospitalized for non-compliance had 166 admissions during study period, with a cost for hospital of about 120,000 Euro.

The most important cause of non-compliance was inadequate income to fill the prescription, which correlated well with the high percentage of elderly patients that have a monthly income below 100 Euro. It is sad but true that we should recommend drugs not only according to the diagnosis and the latest medical studies but also according to the financial possibilities of the patient. Our data are different from previous studies where side effects and forgetfulness were quoted as the most important causes for non-compliance (6,18). Almas (6) reports that 56,8% of patients were non-compliant due to forgetfulness and only 3,48% were non-compliant due to cost issues.

The second most important causes were inadequate instruction combined with an increased number of tablets per day. All of our patients were suffering from chronic diseases, which required life-long treatment. Most of them had a good evolution during hospitalization, with important improvement in life quality; they considered that they were cured for good and stopped medication once they got home; some of them, due to illiteracy, poverty and misconceptions, started visiting providers of non-conventional therapy. It is not surprising that more

complicated medication regimens were associated with inability to recall the regimen (even in patients who really wanted to follow up medical instructions). Patients with a partial recall of their medication regimen were at higher risk than those with no recall, possibly because patients with no recall seek assistance more readily due to rapid worsening of symptoms.

Physical barriers were another important cause of non-compliance. Our data are in accord with other studies (4,6,14). Aged patients are quite willing to respect medical recommendations but they are not able to, which separate them from younger patients who are able to respect medical recommendations but are not willing to, because they deny the importance of their disease.

We believe that the number of non-compliant patients hospitalized during the last 2 years was considerable high. Our data were collected from one of the six medical clinics in Iasi; patients could have been admitted anywhere, depen-

ding on which clinic was on cue for emergencies when the patient needed medical assistance. It is possible that some of our patients were hospitalized elsewhere. More accurate data could have been obtained by gathering information from all medical clinics based on the same type of interview.

The results of our study help identify several characteristics that can be used to identify elderly patients with CDV at risk of non-compliance. These include patients with low income and expensive medical prescriptions, patients with low educational level and sophisticated medical regimens, patients who receive too many drugs, patients with cognitive dysfunction and who live alone, patients who have only partial recall of their medical regimens, smokers and/or alcohol abusers. Our results once again highlight the well-known principle of geriatric clinical pharmacology: prescribe simpler regimens with fewer pills to be taken every day. □

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