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DOI: 10.2478/afmnai-2013-0013

ACTA FACULTATIS
MEDICAE NAISSENSIS

UDC:616-03:616.12-008.331.1

Scientific Journal of the Faculty of Medicine in Niš 2013;30(4):209-218

Original article ■

Medication Adherence in Outpatients with Arterial Hypertension

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SUMMARY

The degree of patient cooperation plays a key role in the success of antihypertensive drug therapy. Non-adherence is the major health and economic problem in the treatment of arterial hypertension (HTA). The aim of the study was to evaluate the degree of adherence in hypertensive patients and to study risk factors affecting adherence and the effects of non-adherence on blood pressure (BP). We performed a cross-sectional study, which involved 170 outpatients with HTA, treated in primary healthcare. Patients were divided into two groups, depending on the degree of adherence, measured using a validated survey form. Statistical analysis was performed using the Pearson's Chi-square and t-test. Good adherence was observed in 126 (74.12%) outpatients. Elderly patients with longer duration of HTA and larger number of drugs in the therapy showed a lower degree of adherence, with more side-effects ($p<0.01$). Patients younger than 65 years were found to be more likely to adhere to their medication regimen, compared to elderly patients ($\chi^2=21.3$; $p<0.01$; OR=6.0 95%, CI 2.76-13.04). Uncontrolled BP occurred in the significantly higher percentage in non-adherent patients (59.1%) compared to the adherent group (21.4%) ($\chi^2=19.84$; $p<0.01$; OR=5.30 95%, CI 2.39-11.85). The most common reason for poor adherence was non-compliance with dosage regimen (27.27%).

The medication adherence rate was found to be low among elderly patients. A poor adherence was found to negatively affect BP control. Determining the factors for non-adherence and developing multidisciplinary intervention programs to address the identified factors are necessary to improve adherence to medication and BP control.

Key words: **adherence, hypertension, factors of non-adherence**

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INTRODUCTION

Arterial hypertension (HTA) is a very important disease from medical and social aspects. HTA usually means the value of blood pressure (BP) ≥140/90 mmHg in the office. However, numerous studies have shown improvement of long-term prognosis by achieving target BP values lower than these. That is why today normal BP is <120/80 mmHg, and systolic pressure in the range of 120-139 mmHg or diastolic in the range of 80-89 mmHg are classified as prehypertension (1, 2).

According to the data published by the Institute of Public Health of Serbia "Dr Milan Jovanovic Batut" in 2006, HTA is one of the most common diseases with constantly increasing tendency and the leading risk factor for cardiovascular and cerebrovascular mortality. In Serbia, the prevalence of hypertension among adults increased from 44.5% in 2000 to 46.5% in 2006. The average systolic BP in 2006 was 134.2 mmHg (136.3 mmHg for men and 131.9 mmHg for women) and diastolic BP was 82.0 mmHg (83.4 mmHg and 80.5 mmHg for men and for women, respectively). In the 4th week preceding the survey, 68.2% of the patients with HTA were regularly taking antihypertensive therapy (3, 4).

The cooperation of the patient with the health care professionals, his/her willingness to adhere to the received advice and guidance and regular medication intake are prerequisites for successful treatment of HTA and prevention of complications. At the beginning of the 21st century, the term “adherence” was introduced, which accurately describes the complex relationship between patients, health care providers and drugs, as the degree of the patient's behavior according to the prescribed therapy in terms of its implementation, dietary measures and regular check-ups (5, 6). Adherence to medication is an important factor in achieving BP control. Patients that were adherent to the antihypertensive therapy were often significantly less likely to have elevated blood pressures. However, there is a strong evidence that many patients with chronic illnesses, including HTA, have difficulty adhering to their recommended therapy. Non-adherence is the major health and economic problem in the treatment of HTA. Identification of risk factors for non-adherence is an important task for all health workers and researchers. It is estimated that the average non-adherence of patients to long-term therapy of chronic diseases in developed countries is about 50% (3, 7, 8). This problem is still insufficiently researched in our country, and there is no data of the degree of adherence in patients and the consequences of non-adherence.

This study was conducted to evaluate the degree of adherence to medications in hypertensive patients and to study the risk factors that might affect medications adherence and the effects of non-adherence to blood pressure control.

PATIENTS AND METHODS

We performed a cross-sectional study, which involved 170 outpatients with HTA (II-IV degree), treated in the primary healthcare in the Niš Region, south Serbia. The data collection period was 24 weeks. Information on the patient’s health and their adherence was obtained through face-to-face interviews with the participants using the validated survey form for medication adherence - 8-item Morisky Medication Adherence Scale (MMAS-8) translated into Serbian for the present study (10). After obtaining patient’s informed consent, they were asked to answer to specific questions during their visit to selected doctor and a pharmacy when they collect prescribed medicines. The extent of adherence to medication was estimated according to the answers of the specific questions.

Each item in MMAS-8 measured a specific adherence behavior, with seven questions that must be answered negatively or positively and with the last one being answered according to a scale of five options: never, almost never, sometimes, often and always. Each response carried a score: yes=0 and no=1, except for the last question: never=1, almost never, sometimes, often, always=0. The total scores were added for each patient. The total score could range from 0 (minimum) to 8 (maximum). Based on the score resulting from the sum of all the answers, the level of adherence was determined. Lower scores would reflect poorer adherence to medication therapy.

In this study, patients were divided into two groups, depending on the degree of adherence, defined on the basis of the MMAS-8. Adherent group (I) consisted of patients who showed satisfactory level of adherence. Patients were considered adherent when they had a score equal to eight or a score of 7 points in the MMAS-8. Non-adherent group (II) represented patients who had low level of adherence. A score of 6 points and below was categorized as non-adherence.

Another questionnaire, which was also used in this study, included 22 questions pertaining to demographics and health status, antihypertensive therapy and total number of drugs taken, laboratory test results, presence of adverse effects of antihypertensive drugs and medication adherence of the hypertensive patients.

Statistical analysis

The data were processed and presented using the SPSS 18.0 commercial statistical program software (IBM Corporation, Armonk, NY). Pearson's Chi-square test (χ^2) with Yates correction and t-test were used when appropriate to compare the differences between adherent and non-adherent groups of patients with HTA. The results were expressed as mean value ± standard deviation (SD). Statistical significance was assigned to $p < 0.05$.

RESULTS

The study included 170 outpatients with HTA. Most of the patients (65.9%) were women. There was no significant difference between adherent and non-adherent patients according to the sex ($p>0.05$). Their ages ranged from 42 to 84 years, with a mean age of 64.5± 11 years. There were more patients (55.88%) below 65 years of age. Figure 1 shows the age distribution of patients with HTA. Only a small percentage of the patients were smokers (10.3%) or alcohol users (6.8%).

Adherence scores obtained in the present study ranged from 0 to 8 (the maximum score possible). From the scores obtained, the patients were categorized either as adherent or non-adherent. Good adherence was observed in 74.12% of the 170 patients sampled. The lower level of adherence was found for patients aged over 65 years. There were 44% of non-adherent patients in the group of patients aged over 65 years, whereas 11.58% were in the patient group younger than 65 years, which was a statistically significant difference ($\chi^2=21.3$; $p<0.01$; OR=6.0 95%, CI 2.76-13.04) (Figure 1).

The largest number of patients had regulated HTA, with the values of BP below 140/90 mmHg. The values of blood pressure in the study group of hypertensive patients, shown in Figure 2, were found to be better among adherers than non-adherers. BP values over 140/90 mmHg were reported in 59.1% of non-adherent patients and in 21.4% of adherent patients, which was also statistically significant ($\chi^2=19.84$; $p< 0.01$; OR=5.30 95%, CI 2.39-11.85).

The average duration of therapy was 18.4±6.3 years (range from 1 to 40 years). In adherent group, the average duration was 11.5±7.4 years, while in non-adherent group it was 25.3±5.2 years. Figure 3 shows the duration of antihypertensive therapy. For the statistical analysis we observed the occurrence of patients with duration of HTA up to 10 years and over (i.e, two groups with age distribution from 0-5 and 6-10 years formed one group which was further compared with another group composed of two subgroups aged 11-20 years and over 20 years). A significant difference was found in the percentage of nonadherers between the group with duration of HTA over 10 years (33%) and the group with HTA duration up to 10 years (16.40%) ($\chi^2=5.12$; $p<0.05$; OR=2.50 95%CI 1.18-5.30).

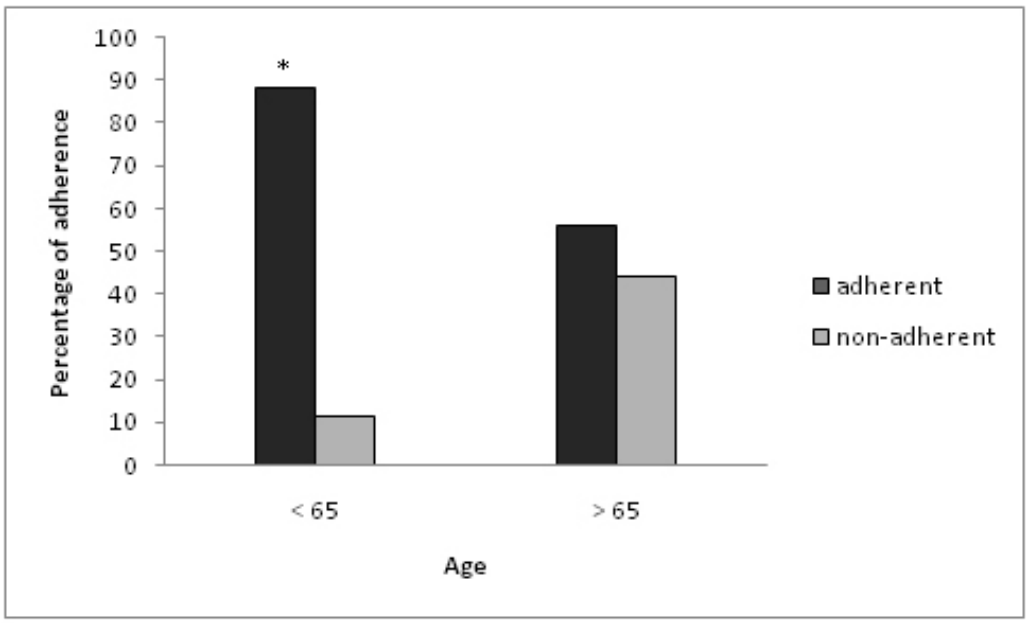
Antihypertensive drugs were used as polytherapy in the study group of outpatients. The combination of diuretics, ACE inhibitors and β blockers (54%) dominated in the adherent group of patients, while the combination of diuretics and β-blockers (59%) was often used in non-adherent patients. The second frequently prescribed drug regimen was a combination of diuretics, β-blockers and Ca antagonists (31%) and the least common one was two-drug therapy with diuretics and ACE inhibitors (7%) in adherent patients. Polytherapy with diuretics, β-blockers and Ca antagonists was prescribed in 11% of non-adherent patients. Two-drug therapy (diuretics + ACE inhibitors and diuretics + angiotensin receptor blockers- ARB) was used in 16% and 14% of non-adherent patients with HTA, respectively.

Reported adverse effects of antihypertensive therapy are shown in Figure 4. The study patients reported 15 adverse effects. Adverse effects were expected, with mild or moderate intensity, and they caused discontinuation of therapy in only 5.29% of patients. Dizziness was the most frequent, more commonly reported in non-adherent (31.8%) compared to adherent patients (4.8%) ($\chi^2=20.47$; $p<0.01$; OR=9.33 95%CI 3.31-26.32). Other side effects were also more frequent in non-adherent patients. In the non-adherent group, 18.2% of patients had a cough, whereas 5.6% of patients had the same adverse effect in the adherent group, which was a statistically significant difference ($\chi^2=4.99$; $p<0.05$; OR=3.78 95%CI 1.28-11.13). Regarding the occurrence of edema, significant difference was also found between the adherent and non-adherent groups, 1.6% and 11.4%, respectively ($\chi^2=5.61$; $p<0.05$; OR=7.95 95% CI 1.48-42.6). Hypotension was found in 6.8% of non-adherent patients and in 5.6% of adherent patients, which was not statistically significant ($\chi^2=0$; $p>0.05$; OR=1.24 95%CI 0.31-5.04). There was also no significant difference between the adherers and non-adherers, 2.4% and 9.1%, respectively ($\chi^2=2.21$; $p>0.05$; OR=4.1 95%CI 0.88-19.10), regarding the occurrence of cramps.

The leading determinants of adherence in the study patients are summarized in Table 1. Elderly patients with longer duration of HTA and larger number of drugs in the therapy showed a lower degree of adherence, with more adverse effects, while the patients who were adherent to medication had less symptoms ($p< 0.01$).

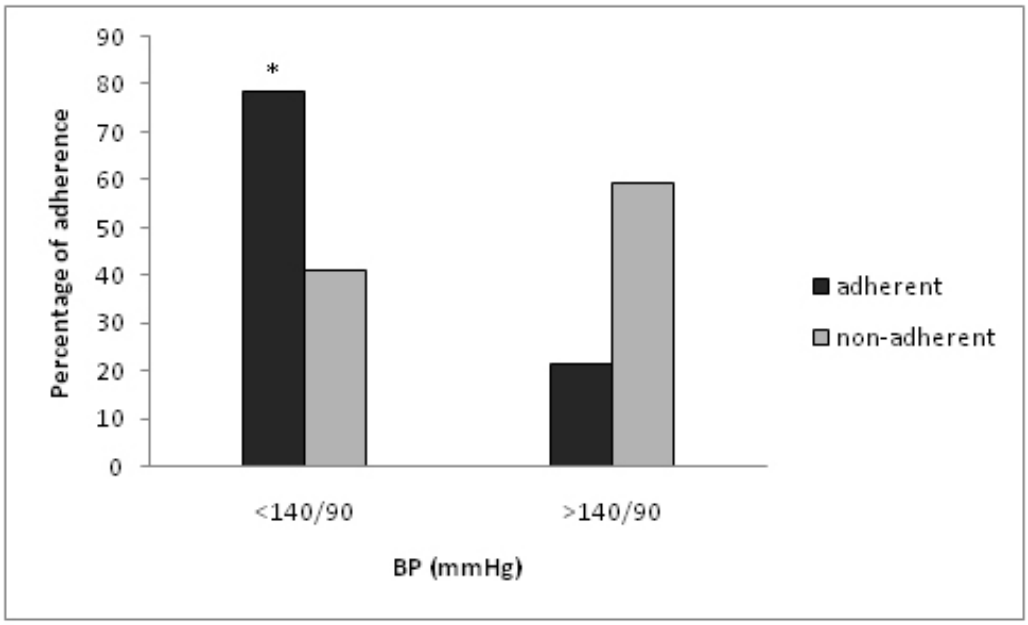
Unsatisfactory level of adherence was noted in 25.88% of hypertensive patients. Figure 5 shows the leading reasons for the low degree of adherence in patients. According to the answers given in our study, the most important factors for the low level of adherence were: isolated non-compliance with dosage regimen (27.27%), isolated forgetfulness (22.73%) and isolated non-regular check-ups (11.36%). All three factors occurred in 38.64% of non-adherent patients involved in the study.

The risk factors for the interruption of antihypertensive therapy are shown in Figure 6. Without consulting a doctor, 15.29% of patients discontinued the therapy. Most of them (58%) independently made this decision because they felt well and it was not necessary to continue with taking medications, or they were afraid of side effects (25%). Some of the patients (17%) discontinued therapy due to financial reasons.



*p<0.01

Figure 1. *Age distribution of hypertensive patients*



*p<0.01

Figure 2. *Blood pressure values in study groups of patients*

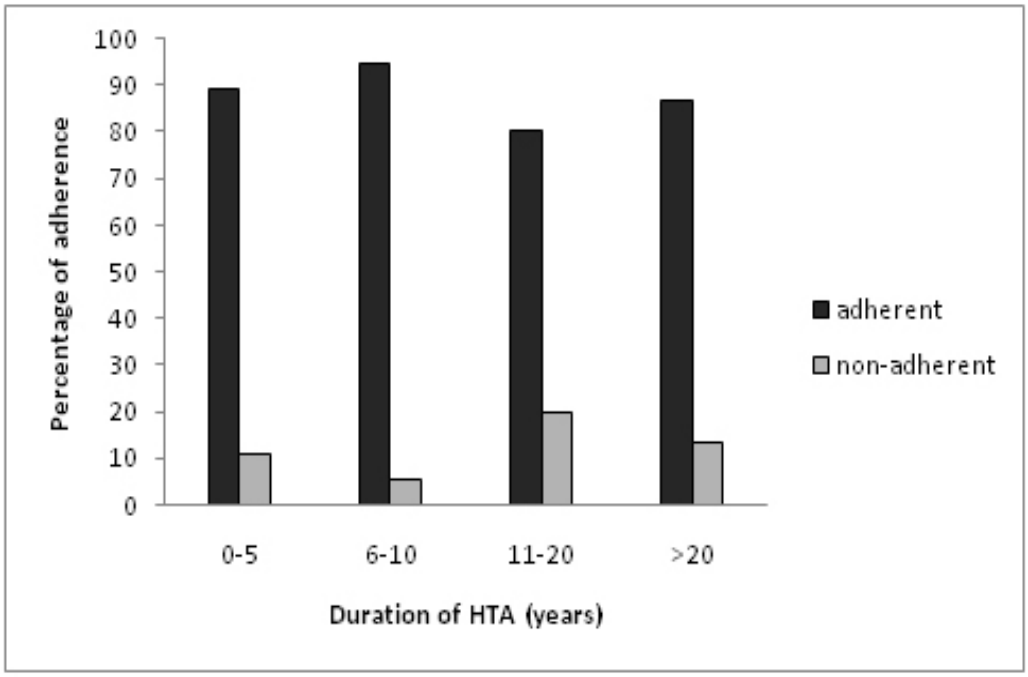
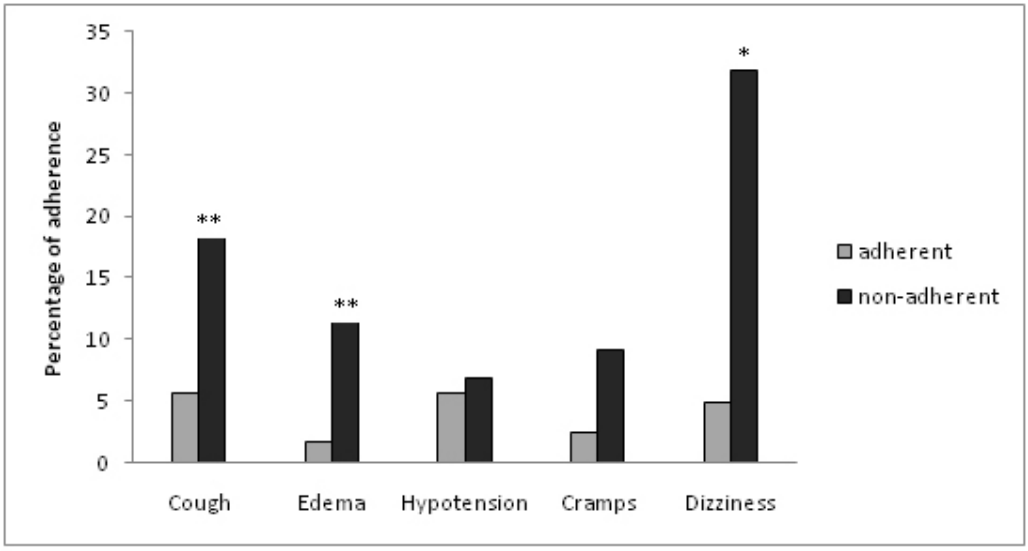


Figure 3. *Duration of antihypertensive therapy*



*p<0.01; **p<0.05

Figure 4. *Adverse effects of antihypertensive therapy*

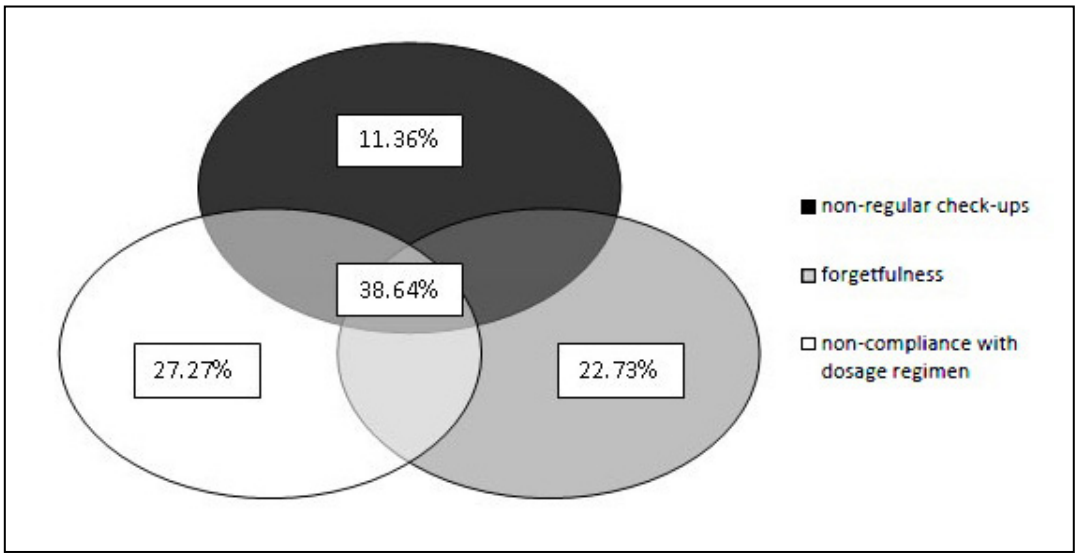


Figure 5. *The leading reasons for the low level of adherence*

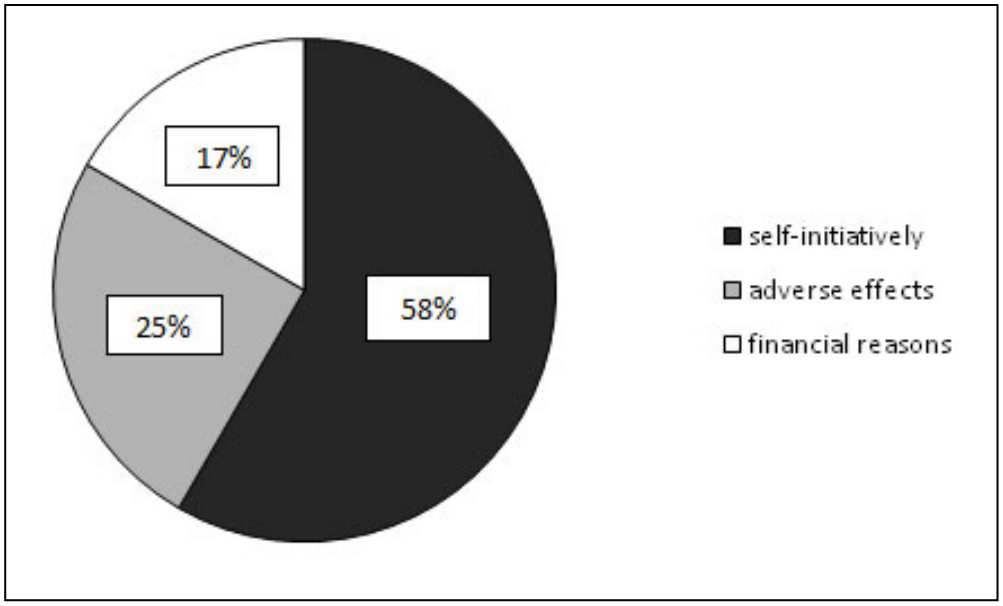


Figure 6. *Reasons for discontinuation of antihypertensive therapy in patients*

Table 1. *Comparison of the leading factors of adherence in the study patients*

Age		Duration of hypertension		Gender		Number of drugs		Adverse effects	
I	II	I	II	I	II	I	II	I	II
61±13	68±9*	11.5±7.4	25.3±5.2*	84F+42M	28F+16M	5±2	6±2	4±2	8±2*

*t-test

DISCUSSION

Adherence to (or compliance with) medication is an important factor that can provide BP control. The term "compliance" is also used as an alternative to "adherence" and suggests that the patient is passively following the doctor's recommendations and that the treatment plan is not based on a therapeutic alliance or contract established between the patient and the physician. On the other hand, "adherence" is the preferred term by many health care providers and considered more accurate because it implies that patients have more autonomy in defining and following their medical treatments.

Since the prevalence of HTA and its complications in the population increase, this problem cannot be ignored from the health and economic aspects. Because of the asymptomatic nature of the disease, low adherence of patients to their prescribed antihypertensive therapy is a widespread problem. The direct and indirect consequences of not taking the prescribed therapy are very important (11-16). Patients' compliance with medication therapy for HTA was reported to vary between 50% and 70% from study to study, based on the study methods employed and the population under study (17). Despite the existence of effective and safe antihypertensive drugs, some studies show that only 30% of patients in the United States achieved adequate control of BP (18). In Croatia, this number is slightly higher and amounts to 41% (3). In the current study, the rate of adherence was found to be 74.12%. The existence of differences between the results from U.S. and European countries can be explained by the limited precision of the method for measuring adherence and the number of our patients. Patients are reluctant to acknowledge irregular therapy or non-adherence to health care professionals because of subjective reasons. Patients have problems with adherence to the defined scheme of drug therapy, either because of personal reasons, forgetfulness and comorbidities, or because of the complicated scheme of treatment, or insufficiently explained meaning of the need for regular intake of prescribed medication. Cognitive and communication factors also affect medication adherence (15).

Our results showed that duration of hypertension and age of patients affected medication adherence. Patients younger than 65 years and those with duration of hypertension less than 10 years were found to be more compliant to their medication regime, compared to elderly patients. A statistically significant lower level of adherence was identified in elderly patients with longer duration of antihypertensive therapy and with reported side effects of drugs. The reason for the lower adherence in elderly patients is the fact that they usually have more associated chronic diseases. It means that they have many drugs prescribed simultaneously, and they often have cognitive disabilities, which increases the chance to use the wrong dosing scheme. Many studies show that the proportion of elderly people in the total population of Europe is growing (19-21). This increases both the number of chronic diseases, and drug consumption (22-25). It was demonstrated in this study that medication adherence can affect the occurrence of adverse drug effects. All reported adverse effects (dizziness, cough, edema, hypotension, cramps) were more common in patients who did not adhere to the prescribed therapy. Target BP values were achieved in the significantly higher percentage in adherent patients compared to the non-adherent group. Uncontrolled BP can cause about serious consequences, including higher rates of mortality and morbidity and economic burden of the health care sector. It can be concluded that adherence to medication is a vital factor that can affect BP control (9).

The low level of adherence in this study was observed in 25.88% of patients. It was caused by non-compliance with therapeutic regimes, forgetfulness and non-regular check-ups, while all three factors were associated in 38.64% of non-adherent patients. Self-initiative discontinuation of antihypertensive therapy before the check-up was one of the risk factors for non-adherence in examined patients. The most common reasons for discontinuation of therapy were the stable condition and patients' attitude that further therapy is unnecessary (58%), occurrence of adverse effects of antihypertensive drugs (25%) and the prices of drugs (17%). Literature data shows that the forgetfulness (60%) is the main reason for non-adherence of patients, then the time of taking the drug (45.4%), lack of drug (44%), polypharmacy (39.5%), drug shortage at the pharmacy (35.9%) or avoiding of adverse effects (29.6%) (3, 18).

The most important factor of adherence to medication is the personal motivation of the patient. Patient knowledge of disease, motivation for treatment, the belief in defined procedure and the expected therapeutic success significantly affect the level of cooperation with a doctor (3). Getting patients involved in their treatments by imparting relevant knowledge often empowers patients to be more concerned about their health. This can be realized through better communication between patients and health care providers. The organization of health services must be restructured to serve patients better, must be adapted to adequate resources and available time for appropriate relationship between doctor and patient. Also, pharmacist's advice to take medication can improve patient's adherence to long-term therapy. Modern approaches for improving adherence include not only the cooperation between health care professionals and patients, but also family members. Team approach which involves the knowledge and practical skills of all team members, with psychoeducation programs, the application of behavioral techniques and individualization of pharmacotherapy may improve the patient's attitude towards treatment, and thus lead to the realization of adequate cooperation.

Intervention programs can improve the degree of adherence. All possible means should be used to enhance patients' memory and to keep to the dosing regimen for their therapy. Steps should be taken by health care professionals through counseling sessions to help patients organize their therapy taking. Better adherence could be achieved by planning of medication taking to correspond with certain activities, such as eating meals, brushing teeth or by setting alarms to go off at medicine taking time. Using of pill boxes, keeping a diary, giving information leaflets to patients and simplifying of dosage regimen will promote adherence in hypertensive patients.

The importance of improving medication adherence to achieve the full benefits of treatment is evident. Adherence provides a better quality of life in patients and prevents adverse reactions which may be the result of non-compliance to defined therapeutic regimes. Thus, efforts should always be made to identify the reasons for non-adherence and the steps to be taken to improve it. The patients should be provided with knowledge of importance to sustain a medication-taking behavior. We believe that by changing the present practice of patient's counseling, giving more advice on how to take medication properly and how to deal with adverse effects of therapy and explaining the importance of adherence to long-term therapy we can upgrade patient's adherence and subsequently therapy effectiveness.

CONCLUSION

The medication adherence rate among hypertensive patients treated in primary care facilities were measured using a standard survey form; it was found to be 74.12%. Our results showed significantly lower levels of adherence in elderly patients with longer duration of antihypertensive therapy and with reported side effects of antihypertensive drugs. A poor adherence rate was found to negatively affect blood pressure control. Irrregular check-ups, non-compliance with therapeutic regimens and forgetfulness are the dominant reasons for inadequate adherence in our hypertensive patients.

The strategies for improving patient's adherence to medication should be developed by taking these findings into account. Therapeutic success of prescribed antihypertensive drugs depends largely on patient adherence. Low patient adherence to prescribed therapy is a current problem from the health and socioeconomic aspects. Determining the factors for non-adherence and developing multidisciplinary intervention programs to address the identified factors are necessary to improve adherence and blood pressure control for better quality of life in patients with arterial hypertension.

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ADHERENCIJA BOLESNIKA SA ARTERIJSKOM HIPERTENZIJOM

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Sažetak

Stepen saradnje bolesnika ima ključnu ulogu u uspešnosti antihipertenzivne farmakoterapije. Neadherentnost predstavlja veliki zdravstveni i ekonomski problem u lečenju hipertenzije. Cilj istraživanja bio je evaluacija stepena adherencije kod bolesnika sa arterijskom hipertenzijom, utvrđivanje faktora rizika za neadherentnost i uticaj neadherentnosti na krvni pritisak. Urađena je studija preseka, kojom je obuhvaćeno 170 bolesnika sa arterijskom hipertenzijom, lečenih u primarnoj zdravstvenoj zaštiti u niškom regionu, u južnoj Srbiji. Bolesnici su podeljeni u dve grupe, zavisno od stepena adherence, utvrđenog na osnovu sprovedenog validiranog upitnika. *Za statističku* analizu podataka korišćeni su Studentov *T-test* i *Hi-kvadrat test.* Zadovoljavajući nivo adherencije zabeležen je kod 126 (74.12%) bolesnika. Stariji bolesnici, sa dužim trajanjem hipertenzije i većim brojem lekova u terapiji pokazali su niži stepen adherencije, sa većim brojem neželjenih efekata ($p<0.01$). Bolesnici mlađi od 65 godina bili su adherentniji u poređenju sa starijim bolesnicima ($\chi^2=21.3$; $p<0.01$; OR=6.0 95%, CI 2.76-13.04). Loše kontrolisan krvni pritisak zabeležen je u značajno većem procentu kod neadherentnih bolesnika (59.1%), u poređenju sa adherentnom grupom (21.4%) ($\chi^2=19.84$; $p<0.01$; OR=5.30 95%, CI 2.39-11.85). Najčešći razlog niskog stepena adherencije bio je nepridržavanje režima doziranja (27.27%).

Kod starijih bolesnika utvrđen je niži stepen adherencije. Ustanovljeno je da neadherentnost negativno utiče na kontrolu krvnog pritiska. Utvrđivanje faktora neadherentnosti i razvoj multidisciplinarnih interventnih programa za uticaj na identifikovane faktore neophodni su za poboljšanje adherencije i krvnog pritiska.

Ključne reči: **adherencija, arterijska hipertenzija, faktori neadherentnosti**