CLINICAL STUDY

# Compliance and the therapeutic effect in patients with arterial hypertension

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**Abstract**

***Objective and method:*** **To analyse the therapeutic effect of treatment in patients monitored in our hypertension outpatient department and evaluation using questionnaires. To determine the influence of treatment effectiveness on the level of co-operation received from the patient. The effect of treatment was monitored by retrospective analysis of the medical records of 101 patients with essential hypertension.**

***Results:*** **1) Pharmacological treatment of essential hypertension led to the normalisation of blood pressure levels in 28 patients. The drop in pressure from 146/90 mmHg to 129/82 mmHg was statistically significant (p=0.001). 2) Only 7 % of patients were fully compliant. A drop ($\delta$) in blood pressure was more marked in compliant patients ($\delta$BPs=11 mmHg, $\delta$BPd=9 mmHg), compared with the group of non-compliant patients ($\delta$BPs=3 mmHg, $\delta$BPd=-4 mmHg). 3) Patients have a low level of compliance in relation to non-medicamentous treatment. They are not willing to cut down their salt intake (37 %), to stop smoking (12 %) and to reduce their weight (11 %).**

***Conclusion:*** **The conducted study confirms the insufficient treatment of arterial hypertension, a better effect of treatment in the patients with 1st stage of arterial hypertension compared with the patients with a more serious stages, a fairly high percentage of non-compliant patients and a positive connection between patient's compliance and the reduction in blood pressure values. We would like to emphasise that long-term compensation of blood pressure is a key factor in preventing complications. The efficiency of treatment depends on regular blood pressure controls and intensive motivation of the patient to respect the therapeutic discipline. *(Tab. 9, Fig. 1, Ref. 17.)***

**Key words: arterial hypertension, compliance.**

Arterial hypertension is a chronic cardiovascular disease with a high prevalence and incidence. A population study in the US demonstrated that optimal control of blood pressure was seen in 35% of examined patients (9). Such a low percentage is boosted not only by insufficient therapeutic intervention, but also by a lack of co-operation – non-compliance of the patient, which in the end leads to a growth in the risk of cardiovascular complications and morbidity.

Compliance can be defined as the ability of the patient to co-operate in the treatment of the disease in question. It is the level of a patient's adherence to the treatment regimen and the level of the patient's capability of adopting changes to their lifestyle (15). The study comparing demographic make-up did not find any correlation between compliance and age, sex, education, income or marital status (10). The basic knowledge with regard to epidemiology, checks and therapy for high blood pressure monitored

the Cuspidi study, which demonstrated a relatively high (60-80%) success rate in the population (6).

The reverse of co-operation (compliance) of a patient is a lack of co-operation (non-compliance). Non-compliance is regarded as everything that is not absolute and complete compliance, inclusive the more partial compliance. (15).

One of the key causes of insufficient co-operation is the fact that arterial hypertension is an asymptomatic chronic disease until cardiovascular complications appear, and so it is possible that

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**Tab. 1. Incidence of non-compliance (%).**

| Type of medication | Ley (1976) | Prescription of drugs | Barofsky (1980) |
|---|---|---|---|
| Antibiotic | 49 | 48 | 52 |
| Psychiatric | 39 | 42 | 42 |
| Anti-hypertensive | | 43 | 61 |
| Antituberculosis drug | 38 | 42 | 43 |
| Other drugs | 48 | 54 | 46 |

Sanson-Fischer, 1995

the patient does not suffer from any subjective difficulties for a long period of time. This state of affairs combined with a lack of co-operation from the physician leads to an increased risk of cardiovascular complications in the patient. The high percentage of incidence of non-compliance in many therapeutic groups of drugs used for treatment of chronic diseases is documented (Tab. 1). In the case of treatment of arterial hypertension it was discovered that an extremely variable percentage of patients did not respect the treatment schedule, and so are non-compliant. It is estimated that around a share of one third to one half of patients have inadequately controled blood pressure as a result of non-compliance in relation to the prescribed anti-hypertensive treatment (3). Other work monitoring compliance of patients to prescribed treatment by the use of the questionnaire method reports a 62 % share of patients that adequately administer the prescribed medicamentous therapy (1). However, with the growing period of illness comes deterioration in the adherence to prescription. 20–50 % of new patients treated for hypertension discontinued the use of pharmacotherapy by one year from having the disease diagnosed

In our work we monitored patient willingness to co-operate with the help of questionnaires and its effect on a drop in blood pressure.

**Methods**

The study was arranged as a cross-sectional study on the basis of retrospective analysis of the medical records of 101 patients with essential hypertension that were treated in the hypertension out-patient department. We analysed data from patients of both sexes by random selection. We gained data from the medical records about initial and final blood pressures (whereby we set the average of the first and last three values recorded at the out-patient department).

As hypertensive was considered a patient with an average systolic pressure above 140 mmHg and with an average diastolic pressure above 90 mmHg. The therapeutic effect was assessed on the basis of a drop in pressure according to WHO/ISH classification from 1999 from a higher to a lower category. We regarded values under 140/90 mmHg as optimal controlled blood pressure.

Patient compliance was assessed on the basis of replies to the questionnaire. For answers in the questionnaire that point to and confirm the insufficient co-operation of the patient, we as-

**Tab. 2. Allocation of minus points in questionnaire for the following replies.**

Concerning adherence to medicamentous therapy:
If the patient stated the non-use or irregular use of medicamentous therapy.
If the patient's prescribed home therapy for high blood pressure does not correspond to the therapy in the documentation.

Concerning adherence to non-pharmacological intervention:
If the patient stated that he was not willing to reduce his salt intake, to lose weight, to give up smoking, reduce alcohol consumption and increase physical activity.

Concerning the effect of treatment:
If the patient, to the question about his status of health, answers that he feels worse or does not notice the effect of treatment.

Concerning internal assessment of compliance:
If the patient himself expressed that he does not act in line with the doctor's orders in the treatment of high blood pressure.

Social factor:
If the patient expresses weak support from his family.

signed minus points (Tab. 2). A compliant patient was a patient without minus points. When the criteria were reduced we considered also deemed a patient with one minus point as a compliant patient.

*Statistic evaluation of results*

The results are given as the arithmetic average and the mean error of the arithmetic average (x±SEM), where n=number of patients in a group. We have expressed the ratios of patients in the group in terms of percentage. Calculations were made with the help of the program Excel 97, Origin 5. We have ascertained the statistic significance with the use of Student T-test. We considered a statistic divergence of $p < 0.005$ as statistically significant.

**Results**

In our study we analysed 101 patients, 47 men and 54 women (Tab. 3). The average age of patients was 58±9 years. Essential hypertension has been diagnosed in the patients in a study 11 years ago (±5 years). In some hypertensive outpatient departments they were treated 6 years on average (±2 years). The initial systolic pressure expressed as the average of three entry measurements was 149±12 mmHg and the diastolic blood pressure was 95±8 mmHg (Tab. 3).

Each patient in the study received medicamentous treatment. At the time of measuring entry blood pressure values only 12 patients had optimaly controlled blood pressure (systolic under 140 mmHg and diastolic under 90 mmHg) (Tab. 4). At the end of the study the number of patients with optimal controlled blood pressure rose to 28. This improvement optimately is of statistical significance (p=0.001). An improvement was also seen in the category of medium hypertension, with the number of pa-

A give up salt
B give up smoking
C increase physical activity
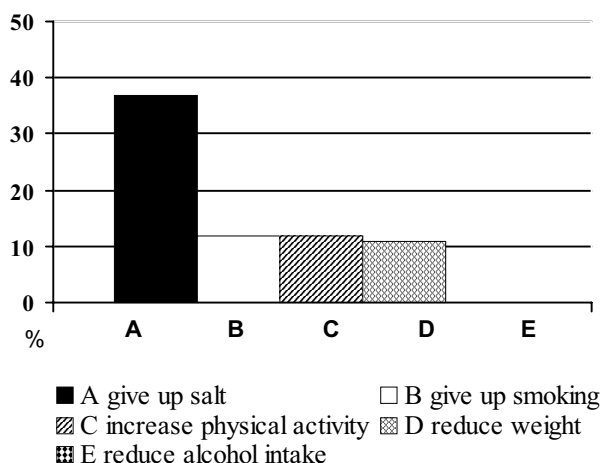D reduce weight
E reduce alcohol intake

**Fig. 1. Patients are not willing to.**

tients dropping from 34 to 16. However, the number of patients with isolated systolic hypertension increased from 7 to 15 (Tab. 4). In patients with a well controlled blood pressure (n=28) we witnessed a drop in pressure from the initial average pressure of 146/90 mmHg to 129/82 mmHg. Patients that did not have their blood pressure under control at the end of the study had a higher blood pressure on average at the beginning of the study 151/92 mmHg, and the average blood pressure of these patients at the end of the study did not change substantially, 150/94 mmHg.

When comparing the entry and final blood pressure there was a drop in pressure from the higher WHO groups to lower groups in 50 % of patients, with a rise in blood pressure in 20 % of patients and no change seen in 30 % of patients during treatment. In the second part of our study we focused on the compliance of monitored patients. We determined compliance indirectly – questionnaire method. From 101 patients only 76 replied to our questionnaire. Table 5 shows entry data of patients divided into groups according to whether or not they replied to the questionnaire. No statistically significant difference was observed in terms of age, baseline pressure or even in the duration of hypertension, but well controlled blood pressure (under the threshold of 140/90 mmHg) at the beginning of monitoring was higher in percentage terms in the group that did not answer the questionnaire (20 % vs 9 %).

In the group of patients that replied to the questionnaire we expected a higher level of compliance. We witnessed a better effect of treatment in this group, although more marked was the statistically insignificant drop in diastolic blood pressure ($\delta=5\pm6$ mmHg vs $\delta=2\pm5$ mmHg) (Tab. 6). The drop in systolic blood pressure was similar in both monitored groups. The percentage of patients with well-controlled blood pressure also rose (under 140/90 mmHg) in the group of patients that replied to the questionnaire from 9 % to 30 % compared with the group of patients that did not reply to the questionnaire (Tab. 6). The difference is substantial in terms of percentage, but at the threshold of statistical importance ($t^2=2.54$).

On the basis of assigning minus points in questionnaires we found that a mere 7 % of patients (n=5) were 100 % compliant.

**Tab. 3. General characteristics of patients.**

| | |
|---|---|
| Patients | n=101 |
| Age (years): | 58±9 |
| Male (n) | 47 |
| Female (n) | 54 |
| Systolic pressure (mmHg) | 149±12 |
| Diastolic pressure (mmHg) | 95±8 |
| Duration of hypertension (years) | 11±5 |
| Treatment in out-patient department (years) | 6±2 |

**Tab. 4. Classification of patients (n=101) to categories according to blood pressure values (mmHg) WHO/ISH classification from 1999.**

| WHO/ISH 1999 | Baseline status | Final |
|---|---|---|
| Optimal | 3 | 2 |
| Normal | 1 | 9 |
| Higher than normal | 8 | 17 |
| Total number of pts with pressure <140/90 mmHg | 12 | 28 |
| I.    Sub-group | 29 | 29 |
| I. | 12 | 10 |
| II. | 34 | 16 |
| III. | 7 | 3 |
| ISH-sub-group | 3 | 10 |
| ISH | 4 | 5 |
| Total number of pts with pressure ≥140/90 mmHg | 89 | 73 |

ISH — isolated systolic hypertension

**Tab. 5. Initial basic data of patients divided into groups of those who replied the compliance questionnaire and those who did not.**

| | Replied n=76 | No reply n=25 |
|---|---|---|
| Age (years) | 58±9 | 55±7 |
| Male (n) | 39 | 8 |
| Female (n) | 37 | 17 |
| Systolic blood pressure (mmHg) | 149±12 | 149±13 |
| Diastolic blood pressure (mmHg) | 94±7 | 96±8 |
| Blood pressure under control (BP 140/90 mmHg) | 9 % | 20 % |
| Duration of hypertension (years) | 11±5 | 11±5 |
| Out-patient treatment (years) | 6±2 | 5±2 |

The drop in pressure in these patients was significant ($\delta$ blood pressure=11 mmHg, $\delta$BPd=9 mmHg). 80 % of patients (n=4) had blood pressure within the normal reference values (Tab. 7).

When mitigating the criteria for compliance and when taking into account also patients with just one minus point, 29 % of patients were compliant (n=22). The drop in systolic pressure in this group of patients was -8 mmHg and diastolic pressure fell on average by 5 mmHg. 41 % of compliant patients had blood pressure under control (Tab. 8).

Non-compliant patients (-2 and more minus points) experienced a lower drop in blood pressure on average. Systolic pressure fell by 3 mmHg and diastolic pressure fell by 4 mmHg.

**Tab. 6. Comparison of data of patients that did not reply to the questionnaire and patients that replyed.**

| | Patients not replying to questionnaire | | Patients replying to questionnaire | |
|---|---|---|---|---|
| | Entry n=25 | Exit n=25 | Entry n=76 | Exit n=76 |
| Systolic blood pressure (mmHg) | 149±13 | 145±10 | 149±12 | 144±11 |
| Diastolic blood pressure (mmHg) | 96±8 | 94±6 | 94±7 | 89±6 |
| Systolic blood pressure <140 mmHg (%) | 32 | 40 | 24 | 39 |
| Diastolic blood pressure <90 mmHg (%) | 28 | 36 | 24 | 53 |
| Systolic+diastolic blood pressure <140/90 Blood pressure (%) | 20 | 20 | 9 | 30 |
| improved | | 40 | | 54 |
| worsened | | 24 | | 17 |
| unchanged | | 36 | | 29 |

**Tab. 7. 100 % compliant patients (n=5) (7 %), without minus points in the questionnaire.**

| | Entry | Exit |
|---|---|---|
| Systolic pressure (mmHg) | 145±7 | 134±7 |
| Diastolic pressure (mmHg) | 97±4 | 88±5 |
| Blood pressure <140/90 mmHg (%) | | 80 |

**Tab. 8. Compliant patients with 0 - (-1) points for questionnaire (29 % (n=22) patients.**

| | Entry | Exit |
|---|---|---|
| Systolic pressure (mmHg) | 149±7 | 141±7 |
| Diastolic pressure (mmHg) | 93±6 | 88±6 |
| Systolic pressure <140 mmHg (%) | | 55 |
| Diastolic pressure <90 mmHg (%) | | 59 |
| Blood pressure <140/90 mmHg (%) | | 41 |

**Tab. 9. Non-compliant patients with 2 or more minus points n-54 (71 %).**

| | Entry | Exit |
|---|---|---|
| Systolic blood pressure (mmHg) | 148±12 | 145±12 |
| Diastolic blood pressure (mmHg) | 94±7 | 90±6 |
| Systolic pressure <140 mmHg (%) | | 31 |
| Diastolic pressure <90 mmHg (%) | | 46 |
| Blood pressure <140/90 mmHg (%) | | 24 |

Only 24 % of patients in this group had well controlled blood pressure (Tab. 9). The difference in the drop of blood pressure in the group of compliant patients and non-compliant patients is clinically significant, but upon statistical assessment of results it is insignificant.

We observed a clinically important trend in the drop in blood pressure. The lack of significance is probably due to the low number of patients in the monitored group.

We analysed certain replies to questions in completed questionnaires. This mostly concerned the subject evaluation of the patient. It is interesting to note that for the question on how hypertension was discovered, only 11 % of patients stated the finding as part of a preventive examination, while 31 % of patients had hypertension diagnosed only after subjective difficulties, 31 % on suspicion of another disease and 27 % of patients claimed that hypertension had been discovered by chance. This fact could contribute to the silent progression of damage to the organs. An improvement in the subjective status after administration of antihypertensive treatment was declared by as much as 75 % of patients. 21 % of patients felt no change and 4 % of patients stated a worsening. As much as 96 % of patients stated that they had used drugs regularly and 78 % claimed thorough adherence to the doctor's instructions. When observing the problem of non-pharmacological treatment, the greatest problem is a reduction of the intake of salt (37 %), followed by smoking (12 %) and increased physical activity and a reduction in weight (11 %).

## Discussion

Via this presented study of the treatment of hypertension in 101 patients we decided to observe the effectiveness of therapy and the correlation between patient compliance and the drop in blood pressure.

Arterial hypertension is one of the key risk factors of cardiovascular diseases. Its long-term silent course causes patients to become disinterested and so the effectiveness of treatment is reduced. Therapy of arterial hypertension is based on two basic principles: a change in lifestyle and pharmacological treatment. Achieving and maintaining a change of lifestyle is extremely difficult for many patients and it is often difficult for them to remember the manner of administration. The stated factors lead to a reduction of therapeutic compliance and weaken self-control of blood pressure, which in turn gradually leads to an increased risk of cardiovascular complications. According to foreign literature, just 25 % to 50 % of patients treated for hypertension have sufficiently controlled blood pressure (140 mm Hg systolic and 90 mmHg diastolic pressure) (17, 14) with 16 % to 50 % of patients discontinuing treatment in the first year. In our work the treatment of hypertensive patients led to a growth in the number of patients with optimally controlled blood pressure (under the threshold 140/90 mmHg) from 12 % to 28 %. Even though statistically the therapeutic effect is highly significant, it is certainly not satisfactory. Patients with optimally controlled blood pressure (n=28) already had a lower blood pressure at baseline examination and the effect of treatment was more marked ($\delta BP=17/7$ mmHg vs $\delta BP=1/2$ mmHg) than in

patients (n=73) that did not experience such a marked drop in blood pressure after treatment.

What is then the cause of such insufficiently controlled blood pressure? One of the factors greatly affecting the result of the therapeutic process is patient compliance together with thorough treatment and checking by the doctor. In our study just 7 % of patients were 100 % compliant, which is a fairly low percentage compared with other studies. The result may therefore be partially affected by a strict system of points. However, we also recorded the most substantial drop in blood pressure in this group of patients (without any minus points).

In this study we opted to use the questionnaire method for determining patient compliance. Literature quotes two basic methods of assessing patient compliance, direct and indirect.

Direct assessment includes the measurement of the levels of active substances, metabolites or level of markers in blood and in urine. Indirect methods determine non-compliant patients fairly well and include the doctor's assessment, personal patient questionnaire, counting tablets (15) and the use of a dosage dispenser with microprocessor. In general indirect methods appear as overvaluating compliance (8), which we attempted to avoid by the strict application of minus points. At the present time the most accurate method of monitoring compliance is considered to be the micro-processor equipped dosage dispenser, with which it is record possible to the exact time and duration the counter is opened, thereby providing precise information also about adherence to time intervals between individual dosages. Analysis of dispensing schemes by Rudd et al found less than a 50 % adherence to the use of the drugs within the recommended time (14). Comparison of the questionnaire method of monitoring compliance in hypertensive treatment with the number of tablets was carried out by Sackett et al (16). The questionnaire method discovered a 78 % share of co-operating patients and upon the use of the method of counting tablets only 48 % were compliant. The percentage share of non-compliant patients was almost the same when comparing these two methods (22 % vs 20 %).

If our work also considered patients with just one minus point as compliant, the percentage of non-cooperating patients reached as much as 75 %. What is the main cause of such a lack of patient compliance? Fear of side effects, addiction and loss of independence are common. In other cases the patient may discontinue the medication, because the symptoms and objective findings either receded or completely disappeared. In terms of medication, there are complex administration systems with frequent dosages, or with the use of various drugs, the similarity of drugs and also the unpleasant taste of the medicament. Some patients reduce their dosage or shorten the duration of treatment in order to save money (3). Many hypertensive patients are asymptomatic and often feel no improvement during treatment. Adverse side effects of drugs could represent one of the other reasons for discontinuing treatment (13). Nelson et al discovered that 69 % of patients that reported adverse effects of drugs were non-compliant compared with 39 % of those not suffering from any adverse effects. The causes of voluntary termination of treatment were monitored by Gallup and Cotugno (5), who discovered that

46 % stopped treatment because they thought they had been cured, 25 % thought that their examining doctor had recommended that they stop the treatment, 11 % did not continue with treatment due to adverse effects of the drugs and 6 % of patients stopped treatment due to a lack of money. From our work on analysis of the replies to questionnaires we can say that the high level of non-compliance was attributed primarily to the inability to change the lifestyle (patients are not willing to reduce salt intake (37 %), stop smoking (12 %) and reduce their weight (11 %) and there is also a fairly high percentage of patients experiencing no subjective improvement in their state (25 %).

We know that older patients are generally more frequent consumers of drugs. It is interesting to note that in the study that monitored non-compliance of polypharmacy in older patients, a high level of compliance in older hypertensive patients was witnessed, even in spite of the fact that costs for treatment were higher on average. Non-compliance was seen in just 14 % of patients (7).

How can we improve patient compliance? One of the basic factors that contributes to the increased level of patient co-operation is to improve the doctor – patient relationship (increased work effectiveness, liquidation of time stress and adapting communication), improving the education of the patient, his knowledge about the diseases and about the drugs by the clearest and simplest provision of information possible. Improving family and social support also greatly contributes to a good result of the therapeutic process. Educational seminars have also proved effective (4) as well as individual consultations (17).

An alarming fact is also the lack of primary prevention of cardiovascular diseases. An 11 % share of the diagnostics of increased blood pressure in preventive examinations can partially be blamed for the increasing share of cardiovascular diseases, the organ structure of changes, worsened prognosis of the patient, extended length of hospitalisation and increasing costs.

The conducted study confirms the insufficient therapeutic effect of the treatment of arterial hypertension, the better effect of treatment in patients with 1st stage arterial hypertension. There is a positive influence of patient compliance on a reduction in the blood pressure values. In our work we can find a fairly high percentage of non-compliant patients and a low level of primary prevention of cardiovascular diseases. We would like to emphasise that regular controls of blood pressure and intensive motivation of the patient to adhere to the therapeutic discipline improve the control of hypertension and reduce the risk of cardiovascular disease and last but not least, reduce costs for hospitalisation of patients.

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