Economic justification of blood pressure lowering costs in the complex therapy of arterial hypertension with Cholecalciferol supplementation

Introduction
The prevalence of arterial hypertension (AH) among the representatives of adult population accounts for 30-45%, while among the subjects over 60 it reaches 60% [1]. Unfortunately, at present, despite the wide range of antihypertensive medications, fewer than 50% cases getting therapy reach the office values of systolic blood pressure (SBP) under 140 mmHg [1, 2]. The SBP rate of ≥140 mmHg is associated with an advanced mortality and disability in ~70% cases; furthermore, most SBP-associated lethal outcomes occur during the year due to the ischemic heart disease (4.9 million), hemorrhagic (2.0 million) and ischemic strokes (1.5 million) [3]. Both office and out-of-office AH values have an independent and continuous correlation with the stroke, myocardial infarction, sudden death, heart failure, peripheral arteries’ disease, atrial fibrillation frequency, as well as with the terminal renal failure, cognitive dysfunction and dementia [4-7]. Both previous and recent metaanalyses reveal that the SBP reduction under 140 mmHg promotes the relative risk reduction for all the cardiovascular events (including mortality); a similar positive effect is observed with the SBP reduction under 130 mmHg [8]. The data of recent metaanalysis demonstrate that with the initial SBP rate of over 160 mmHg, its reduction by every 10 mmHg to 130-139 mmHg promotes the reduction of key cardiovascular events frequency and mortality rate [9]. The positive effect of reduced SBP rate amounting to 130 mmHg resulted in the revision of target values among the AH pa...
patients, the fact reported by the 2018 ESC/ESH guidelines for the management of arterial hypertension [10].

According to the most recent publications, the hypovitaminosis D affects over 1 billion people across the world [11, 12], emphasizing the inevitable high AH comorbidity. The results of several metaanalyses including randomized placebo-controlled trials demonstrated a significant reduction of both SBP (-6.2 (-12.32; -0.04) mmHg) and diastolic blood pressure (DBP) (-3.1 (-5.5; -0.6) mmHg) in the AH patients taking Vitamin D supplements rather than placebo [13-15]. The most pronounced SBP-reducing effect (by 14 mmHg in comparison with placebo) was registered with a single Ergocalciferol dose of 100,000 IU in the placebo-controlled trial [16]. The dose of Cholecalciferol amounting to 2,000 and 4,000 IU per day reduced the SBP rates by 3.4 and 4.0 mmHg, respectively (p = 0.04) [14]. Despite the fact that the findings of clinical trial evaluating the Vitamin D supplement efficacy in terms of arterial BP reduction are disputable, the hypovitaminosis D requires correction. Taking into account the fact that the Cholecalciferol use entails the arterial BP reduction effect among the AH patients, this option is to be tackled in order to increase the efficacy of both conditions’ improvement.

The aim of this study is to calculate the cost effectiveness of the complex antihypertensive therapy with/out Cholecalciferol in terms of arterial BP reduction.

**Materials and methods**

We have performed a prospective, controlled, randomized, comparative, unicentral clinical trial of patients with an essential AH of Grade II. The verification of AH diagnosis was made according to the ESH/ESC Guidelines for the management of arterial hypertension [17]. Among the exclusion criteria, there are: symptomatic AH, acute coronary or cerebrovascular pathology, chronic heart failure over II NYHA class, hemodynamically relevant cardiac rhythm disorder requiring the constant use of antiarrhythmic medication, glucocorticoid use, sarcoidosis, active pulmonary TB form, bronchial asthma, chronic obstructive lung disease, active inflammatory process of any localization, chronic kidney failure with creatinine clearance of 60 mL/min and below, liver function disorder, diabetes mellitus, oncological diseases, anemia and other concomitant diseases potentially affecting the studied parameters. The study protocol was approved by the Bioethics Committee of the Grodno State Medical University. While admitting patients into the trial, we’ve made an alphabetic ranking of 154 patients. Irrespective of the initial Vitamin D blood rate, everyone in two patients received Vitamin D (Cholecalciferol in a dose of 2,000 IU/day) along with an antihypertensive therapy; these patients made the principal group (AH(+CH)). During the next 3 months, 78 subjects were taking Cholecalciferol; during 6 months, 20 subjects were taking Cholecalciferol; during 8.7 ± 2.1 months on average, 9 patients continued the Cholecalciferol use. The reference group (AH(-CH)) was made of the subjects who were not taking any Cholecalciferol. All the patients were examined at the stage of inclusion (initial examination) and once again after 12 months at least and after 18 months at most (on average after 15.4 ± 1.9 months). 78 patients of AH(+CH) group completed the trial participation, and 76 patients of AH(-CH) group did the same thing.

The evaluation of Vitamin D supplementation rate was based on the 25(OH)D total blood rate by means of immunoenzyme analysis. The assay was performed at the Grodno State Medical University’s research laboratory, using the original «DRG» (Germany, Marburg) reagents. The 25(OH)D blood rate of under 20 ng/mL was considered deficient, 20-30 ng/mL was considered insufficient and 30-80 ng/mL was considered optimal.

The information on medication cost in the Republic of Belarus was obtained from the electronic “Pharma-service” database (www.tabletka.by). The number of days in treatment was calculated on condition that the patients were taking the assayed medication in a dose of no less than 90 % prescribed (0.9) for 80 % days per year (0.8) [18].

In order to evaluate the cost effectiveness of complex antihypertensive therapy along with Cholecalciferol and diuretics, the patients were united into the following groups:

- D(-)CH(-) group (n = 52) – subjects who did not take either diuretics (as a part of combined antihypertensive therapy) or Cholecalciferol (to correct the Vitamin D level);
- D(-)CH(+) group (n = 47) – subjects who did not take diuretics though took Cholecalciferol in a dose of 2,000 IU/day every day;
- D(+)CH(-) group (n = 24) – subjects who did not take Cholecalciferol though took diuretics as a part of combined antihypertensive therapy;
- D(+)CH(+) group (n = 31) – subjects who were taking both diuretics and Cholecalciferol in a dose of 2,000 IU/day every day.

The duration of Cholecalciferol use in the D(-)CH(+) group took 4.5 ± 2.3 months, while the duration in the D(+)CH(+) group took 4.4 ± 2.2 months; it did not differ among the groups.

The statistical processing of results was performed using «Statistica 10.0» software. The data was presented as absolute values, as percentage, as a median (Me) and an interquartile range (Q25-Q75), as well as mean value and standard deviation (M ± SD) depending on the character of their distribution (Shapiro–Wilk test). The correlation between variables was represented by r-Spearman’s coefficient. The “dynamics” value was calculated as a difference of values before and after the prescribed treatment. The zero-hypothesis was rejected at the level of p < 0.05.

**Results**

During the prospective treatment, all patients were taking the combined antihypertensive therapy, medication use and their mean doses in the AH(-CH) group and
AH(+CH) group were presented in Table 1. It is obvious that the groups did not differ in terms of medications they were taking.

The AH(-CH) group and AH(+CH) group were age-matched (51.1 ± 8.7 and 52.0 ± 6.0 years, respectively), gender-matched (59 women, 17 men and 65 women, 13 men respectively), the AH duration-matched (5.0 (3.0; 10.0) and 5.0 (3.0; 10.0) years, respectively), body mass index-matched (31.2 (27.4; 34.9) and 29.4 (25.8; 33.0) kg/m², respectively) and 25(OH)D blood level-matched (Table 2).

The frequency of deficiency, insufficiency, optimal level of Vitamin D did not differ across the groups, as reflected by Fig. 1.

At the final examination, the optimal Vitamin D level was registered in 83 % of the participants from AH(+CH) group more frequently (p = 0.001) than from the AH(-CH) group, and more frequently (p = 0.0001) compared to the original data. The Vitamin D deficiency was observed less frequently in the AH(+CH) group (p = 0.0008) than in the AH(-CH) group, and in comparison to the initial data (p < 0.00001). In the AH(+CH) group, the insufficiency was diagnosed more rarely in comparison to the initial data (p = 0.006), and its rate didn’t differ significantly across the groups (p = 0.25). During the follow-up examination, the 25(OH)D blood level grew in both groups in comparison to the initial data. However, it got considerably higher in the AH(+CH) group (p = 0.0000001) than in the AH(-CH) group. The growth dynamics in the AH(+CH) group was significantly more noticeable (p = 0.000005) than in the AH(-CH) group (Table 2).

Table 1. Prospective observation of antihypertensive therapy in the AH groups taking Cholecalciferol (+CH) and not taking Cholecalciferol (-CH).

| Medication/mean dose | AH(-CH), n = 76 | AH(+CH), n = 78 |
|----------------------|----------------|----------------|
| Ramipril, % mean dose, mg | 78 | 82 |
| 8.5 (5.0; 10.0) | 7.5 (5.0; 10.0) |
| Losartan, % mean dose, mg | 22 | 18 |
| 50.0 (50.0; 100.0) | 50.0 (50.0; 100.0) |
| Indapamide, % mean dose, mg | 21 | 19 |
| 1.59 ± 0.28 | 1.65 ± 0.36 |
| Hydrochlorothiazide (HCTZ), % mean dose, mg | 58 | 63 |
| 13.8 ± 3.9 | 12.9 ± 2.3 |
| Amlodipine, % mean dose, mg | 18 | 16 |
| 5.0 (5.0; 10.0) | 5.0 (5.0; 10.0) |
| Bisoprolol, % mean dose, mg | 24 | 18 |
| 5.0 (5.0; 10.0) | 5.0 (2.5; 5.0) |

Notes (for table 1 and 2): AH(+CH) – patients who received Cholecalciferol along with an antihypertensive therapy; AH(-CH) – subjects who received only antihypertensive therapy.

Table 2. Antihypertensive therapy costs, values and dynamics of arterial blood pressure and Vitamin D level in the groups of patients taking Cholecalciferol AH(+CH) and abstaining from it AH(-CH).

| Index | AH(-CH), n = 76 | AH(+CH), n = 78 |
|-------|----------------|----------------|
| 25(OH)D, ng/mL | initial | 21.2 (13.3; 32.9) | 23.2 (16.2; 33.0) |
| follow-up | 31.3 (24.5; 39.7) | 41.3 (32.5; 55.0) |
| Δ 25(OH)D, ng/mL | 8.2 (2.6; 16.3) | 22.3 (7.6; 34.9) |
| Antihypertensive therapy cost in the group during the entire observation | 6952 $ | 7793 $ |
| Cholecalciferol costs | - | For the entire group +540 $ |
| Antihypertensive therapy per capita cost during the entire observation | 91.5 $ | 106.8 $ |
| Systolic blood pressure, mmHg | initial | 140 (130; 150) | 130 (127.5; 140)* |
| follow-up | 130 (120; 140)* | 130 (127.5; 140)* |
| Δ Systolic blood pressure, mmHg | -8.9 ± 14.7 | -16.6 ± 18.80 |
| Systolic blood pressure per capita reduction cost by 1 mmHg | 10.3 $ | 6.4 $ |
| Diastolic blood pressure, mmHg | initial | 90 (80; 97.5) | 80 (80; 90)* |
| follow-up | 80 (80; 90)* | 80 (80; 90)* |
| Δ Diastolic blood pressure, mmHg | -6.4 ± 9.9 | -8.8 ± 11.4 |

Notes: * – p < 0.05 compared to AH(-CH); # – p < 0.05 compared to the initial data.
After 3 months of the Cholecalciferol use, the highest 25(OH)D increase (27.8 (19.2; 40.9) ng/mL) was observed in those subjects with an initial Vitamin D deficiency of 12.0 (8.1; 16.3) ng/mL and post-therapy 25(OH)D level of 41.3 (36.7; 50.0) ng/mL (p = 0.000006), as Figure 2 depicts.

Among the subjects with an initial Vitamin D deficiency, the optimal level was achieved by 89 % cases. The subjects with an initial 25(OH)D insufficiency (24.4 (22.2; 27.1) ng/mL) had its level significantly (p = 0.000001) growing (40.3 (34.7; 42.9) ng/mL); its increase being 20.1 (7.8; 34.9) ng/mL. The optimal level was reached by 81 % cases. The subjects with an initially optimal 25(OH)D level (38.1 (33.7; 44.1) ng/mL) had no significant growth registered; it amounted to 46.2 (43.2; 48.3) ng/mL, its growth being 1.4 (–4.6; 16.4) ng/mL. The upper threshold of optimal 25(OH)D level was not exceeded.

During the follow-up examination, both groups reported the reduced SBP and DBP; in the AH(+CH) group, the SBP decrease was more pronounced (p = 0.005) than in the AH(-CH) group (Table 2).

As it is evident from Table 3, at the background of the ongoing therapy there was a significant SBP and DBP reduction compared to the initial data (p < 0.05 in all cases). After the trial was completed, the groups did not differ in terms of SBP or DBP (p < 0.05 in all cases); however, the negative dynamics of SBP or DBP was the most pronounced in the D(+)CH(+) group, it differed significantly from the similar index in all the groups. At the end of trial, the 25(OH)D level grew to a considerable extent (p < 0.05) in comparison to the initial values of the D(+) group. However, this group also reported the highest overall cost of treatment (129.5 $ per capita), the per-capita expenses for the antihypertensive therapy within a complex Cholecalciferol treatment diminished by 64.74 $ in comparison with the patients receiving only antihypertensive treatment. The target SBP values (< 140 mmHg) were achieved by 63.5 % patients in the AH(-CH) group and 79.5 % patients in the AH(+CH) group (p = 0.03). The target DBP values (< 90 mmHg) were achieved by 89.5 and 88.4 % patients, respectively (p > 0.05); the DBP reduction dynamics between the groups did not differ either. This way, the costs of SBP reduction are more economical in case of the complex therapy with Cholecalciferol, whenever the target values are reached more frequently.

The “cost effectiveness” contrastive analysis of the arterial BP reduction by means of diuretics and Cholecalciferol accounting for the antihypertensive therapy demonstrated that the lowest cost of per capita BP reduction by 1 mmHg is associated with Cholecalciferol (Table 3). Although the Cholecalciferol addition increased the overall cost of treatment (129.5 $ per capita) in the D(+)CH(+) group. However, this group also reported the highest SBP reduction (-27.4 mmHg), i.e. the cost of SBP reduction by 1 mmHg per capita is 4.7 $. At the same time, although the D(-)CH(-) group is associated with the lowest cost of treatment (82.0 $ per capita), the SBP dropped by 8.7 mmHg only. In this group, the SBP reduction by 1 mmHg per capita cost 9.4 $, being twice as high as the similar cost in the D(+)CH(+) group. In the D(+)CH(-) group, the cost of SBP reduction by 1 mmHg per capita was 7.1 $, which is 2.4 $ more than in the D(+)CH(+) group,
i.e. in order to reduce the SBP by 27.4 mmHg, one should spend 65.76 $ per capita. The effort of per capita SBP reduction by 1 mmHg turned out to be less cost-effective in the D(-)CH(+) group, where the cost was 2.3 times higher, i.e. 10.6 vs. 4.7 $ in the D(+)-CH(+) group. As it is evident from Table 3, the similar results were obtained for the DBP, though with a lower cost-effectiveness. This way, it is clear that the SBP and DBP reduction costs were the lowest in case of the group treated by a complex therapy involving Cholecalciferol and diuretics. The highest arterial BP was also observed in this group.

While prescribing the AH therapy, the healthcare provider has a twofold purpose: to achieve the target arterial BP values and prevent the hypertension crises, and to reduce the overall risk of cardiovascular events and their lethal outcomes. For the latter purpose, one should maintain stable target arterial BP values, i.e. a complex clinical practice issue. In the modern circumstances, the patients are often imposing their own perspective of complex therapy costs. The medical journals feature but a few articles evaluating its cost effectiveness. Our calculations demonstrate that the most expensive therapy may turn out to be more cost effective to achieve the long-term purposes.

**Conclusions**

Our findings prove that the complex AH treatment involving Cholecalciferol entails not only the arterial BP correction but also the Vitamin D status improvement. Using Cholecalciferol in a dose of 2,000 IU per day during 3 months results in an achievement of optimal Vitamin D level in 83 % cases, irrespective of the antihypertensive therapy. It does not modify the Vitamin D level if it was optimal at the beginning. If Cholecalciferol was taken in a dose of 2,000 IU per day during 6.5-12 months, one may achieve the optimal Vitamin D level in 100 % cases. The most pronounced dynamics of 25(OH)D blood level increase with Cholecalciferol occurs at the initial 25(OH)D level of < 20 ng/mL.

**Table 3. The complex antihypertensive therapy cost, values and dynamics of arterial blood pressure and Vitamin D level**

| Index | D(-)CH(-) | D(-)CH(+) | D(+)CH(-) | D(+)CH(+) |
|-------|-----------|-----------|-----------|-----------|
| n     |           |           |           |           |
| 52    | 47        | 24        | 31        |
| 25(OH)D, ng/mL | | | | |
| initial | 24.9 (18.2; 27.2) | 22.8 (17.3; 26.2) | 17.4 (15.3; 21.7) | 23.5 (18.4; 27.1) |
| follow-up | 33.7 (29.2; 42.2) | 48.9 (31.3; 58.2)* | 26.1 (13.3; 33.8) | 36.8 (30.4; 47.6)* |
| | | | | |
| Antihypertensive therapy cost in the group during the entire observation | 4266 $ | 4297 $ | 2954.6 $ | 3705.1 $ |
| Cholecalciferol costs | – | +470 $ | – | +310 $ |
| Antihypertensive therapy per capita cost during the entire observation | 82 $ | 101.4 $ | 123.1 $ | 129.5 $ |
| Systolic blood pressure, mmHg | | | | |
| initial | 140.0 (130.0; 140.0) | 140.0 (140.0; 150.0) | 140.0 (130.0; 155.0) | 160.0 (150.0; 160.0) |
| p<0.001 | p<0.001 | p<0.001 | p<0.001 |
| follow-up | 130.0 (120.0;140.0)* | 130.0 (125.0; 140.0)* | 127.5 (120.0; 137.5)* | 130.0 (130.0; 140.0)* |
| Δ Systolic blood pressure, mmHg | –8.7 ± 16.1 | –9.6 ± 14.7 | –17.3 ± 14.9 | –27.4 ± 17.9 |
| p<0.001 | p<0.001 | p<0.001 | p<0.001 |
| Systolic blood pressure per capita reduction cost by 1 mmHg | 9.4 $ | 10.6 $ | 7.1 $ | 4.7 $ |
| Diastolic blood pressure, mmHg | | | | |
| initial | 90.0 (80.0;100.0) | 90.0 (90.0; 100.0) | 90.0 (87.5; 92.5) | 95.0 (90.0; 100.0) |
| follow-up | 80.0 (80.0;90.0)* | 80.0 (80.0; 90.0)* | 80.0 (80.0; 87.5)* | 80.0 (80.0; 90.0)* |
| Δ Diastolic blood pressure, mmHg | –6.40 ± 12.99 | –7.0 ± 10.4 | –8.6 ± 9.5 | –12.1 ± 11.2 |
| p<0.001 | p<0.001 | p<0.001 | p<0.001 |
| Diastolic blood pressure per capita reduction cost by 1 mmHg | 12.8 $ | 14.5 $ | 14.3 $ | 10.7 $ |

Notes: * – p < 0.05 while comparing the initial and follow-up data; p< - significance of differences in comparison with the D(-)CH(-) group; p< - significance of differences in comparison with the D(+)CH(+) group; p< - significance of differences in comparison with the D(+)CH(-) group; p< - significance of differences in comparison with the D(+)CH(+) group.
The complex AH therapy involving Cholecalciferol is most often associated with a significant reduction of SBP target rates and is more cost efficient than the antihypertensive therapy alone. The highest SBP and DBP reduction and the lowest expense range was reported for the complex AH therapy involving Cholecalciferol and diuretics.

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1. V. V. Yakubova. Collation and processing of material, analysis of the findings, writing the text.

2. V. A. Snezhitskiy. Concept and design of the study.

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Економічне обґрунтування витрат на зниження артеріального тиску при комплексній терапії артеріальної гіпертензії з прийомом холекальциферолу

Резюме. Метою дослідження був розрахунок витрат на зниження артеріального тиску (АТ) при комплексній терапії артеріальної гіпертензії (АГ) з прийомом холекальциферолу і без нього. Матеріали та методи. 154 пацієнта з АГ II ступеня були розподілені в групу, яка приймала комбіновану антигіпертензивну терапію і холекальциферол 2000 МО/добу (АГ(+Х)), і групу порівняння (АГ(–Х)). Вимірювали офісний артеріальний тиск, рівень загального вітаміну D в крові. Розраховували витрати на медикаментозну терапію. Результати. При повторному обстеженні рівень вітаміну D в крові підвищився і в групі АГ(+Х) став вище (p = 0,0000001), ніж у групі АГ(–Х). Вартість медикаментозної терапії на 1 людину в групі АГ(+Х) була вищою, ніж у групі АГ(–Х) (106,8 і 91,5 $. відповідно), проте вартість зниження 1 мм рт. ст. систолічного тисків має більшою. Стоимость снижения артериального давления при комплексной терапии артериальной гипертензии с использованием холекальциферола, особенно в сочетании с диуретиком. Крім того, при комплексній терапії ми отримали корекцію не тільки АТ, але і статусу вітаміну D в організмі.

Ключові слова: вітамін D; артеріальна гіпертензія; витрати; економічна ефективність; холекальциферол; артеріальний тиск.