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Cost-effectiveness analysis of psychotherapy in treatment of essential hypertension in primary care

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Summary

Aim of the study. To estimate expediency of psychotherapy in patients with essential hypertension from a clinical and economic perspective.

Place and duration of study. Clinical material was collected from September 2011 to February 2012 in Polyclinic no. 12, Almaty and the Central City's Polyclinic, Kaskelen.

Method. 75 patients with identified psychosomatic disorders (37 male, 38 female) suffering from hypertension of a first or second degree (from 140/90 to 179/109mmHg) were randomised into two groups (mean age 48.5±3.69 and 47.5±4.2 years). All patients received therapy within the same scheme, but group 1 was additionally treated with psychotherapy.

Results. Qualitative improvements were shown on all scales of the "Mini-mult" test for group 1. The control examination of mean blood pressure (BP) at week 14 found a statistically significant difference in final systolic blood pressure (SBP) between the two groups (134.27±3.7 vs. 137.33±3.9, p=0.032), but no such difference in final diastolic blood pressure (DBP) (82.93±5.1 vs. 83.81±4.3, p=0.198). The average cost of the 24-week treatment per person was 47.81USD for group 1 (standard treatment with psychotherapy) and 48.62USD for group 2 (standard treatment). The cost of SBP reduction was 1.98 vs. 2.53USD per 1mmHg for group 1 and 2 respectively and for DBP reduction it was 3.19 vs. 3.73USD per 1mmHg for group 1 and 2 respectively. Blood pressure (BP) reduction was faster in group 1 (7.05 vs. 7.97 weeks).

Conclusions. Conservative treatment of hypertension combined with comprehensive psychotherapy leads to better results compared with a conventional conservative treatment scheme, from psychological, clinical and economic points of view, bur results can be different in another country. More trials in different countries with greater numbers of patients are necessary.

hypertension / psychosomatic diseases / psychotherapy / cost-effectiveness analysis adoptive family research methodology / adoption / adoptive family

INTRODUCTION

According to the WHO Regional Office for Europe database, every year 30,000 new cases of arterial hypertension (AH) are identified in the Republic of Kazakhstan [1]. Kazakhstan national statistical bulletin informs about the prevalence of AH cases at up to 1970.18 per 10,000 people in 2012 [2]. According to various researchers, the prevalence of AH in Kazakhstan varies from 15.2 to 27%, with an almost equal level of prevalence in the urban and rural areas, which is comparable with international data [3]. The standard treatment for established hypertension is antihypertensive medications, diet and exercise. The effectiveness of a combined conservative treatment was confirmed in many trials (ABC-GP study [4], STRATHE [5]) [AQ1. Please note references added to the two trials, correct?]. For patients in the prehypertensive blood pressure range, lifestyle changes are the primary intervention, unless the patient has multiple risk factors. As is generally known, in 1950 the American scientist Alexander attributed AH to the "golden seven" psychosomatic diseases [6], which explains the effect of psychotherapy in the treatment of this illness. The positive effect of psychotherapy on high blood pressure has been confirmed in various studies. Psychotherapeutic assistance in Ka-

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zakhstan is provided at the primary outpatient level, which allowed us to test psychotherapy for the treatment of arterial hypertension.

Hypertension has a tremendous impact on the health of the American public. According to the American Heart Association, the total estimated cost of hypertension in 2007 was 66.4 billion USD [7]. From the modern standpoint of health management, the effective organisation of health care takes into account not only the clinical parameters, but also the economic costs.

Our objective was to evaluate the appropriateness of psychotherapy in patients with essential arterial hypertension (EAH) from the clinical and economic standpoint.

METHOD

The study was a clinical randomised controlled trial (RCT) combined with economic analysis. Seventy-five patients suffering from EAH were selected. The selection criterion was hypertension of a first or second degree (blood pressure (BP) within 140/90 and 179/109mmHg, as specified in the JNC 7 report) lasting at least 6 months [8]. In addition, all patients were tested using the standard psychodiagnostical tests: the Minnesota Multiphasic Personality Inventory (MMPI), the Giessen Complaint Questionnaire and the questionnaire on psychosomatic complaints [AQ2. Please provide references to all three tests]. We excluded patients suffering from secondary arterial hypertension (due to diabetes mellitus, ischemic heart disease, cardiomyopathy, kidney disease, asthma, respiratory disease, cardiac disease [AQ3. Please note "disease" added in both cases, OK?], renal failure, cancer), patients with organic lesions of the central nervous system and those with psychiatric illnesses (schizophrenia, anxiety and phobic disorders, emotive sphere [AQ4. What was meant by "emotive sphere", was that "emotional disorders"? It is possible to give any examples?]). Patients received recommendations for the normalisation of blood pressure (restricting alcoholic beverages, reducing salty foods, monitoring fluid intake, quitting smoking, observing work and rest periods).

PARTICIPANTS

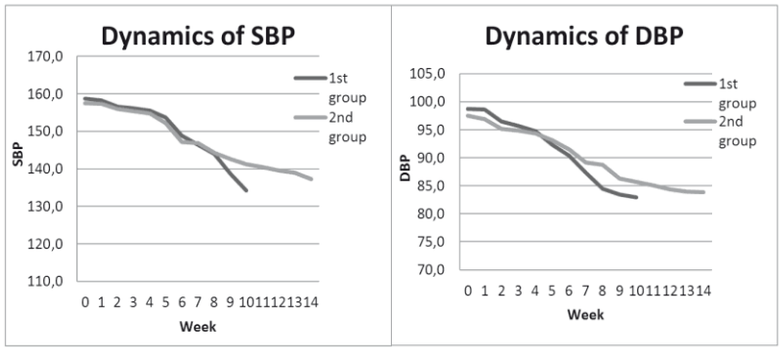
The selected contingent was randomly divided into two groups. The first group (group 1; N=40) were patients receiving antihypertensive therapy and symptomatic psychotherapeutic correction. The second group (group 2; N=35) were patients receiving only antihypertensive therapy. Patients visited every 2 weeks after the first visit, at 4, 6, 8, 10 weeks, etc., to achieve the target blood pressure (<140/90mmHg). Follow-up took place at week 24. As criteria for the effectiveness of the conservative treatment, we used significant reduction in blood pressure and number of visits required to achieve that (quality-adjusted life-year (QALY) was rejected due to study design limitations, namely a short follow-up period). All patients underwent the "small MMPI test" (Mini-Mult) at the beginning and at follow-up, and Tukaev's test scale (a scale developed by the neuropsychiatric research Institute [AQ5. Is this the Psychoneurological Research Institute in St Petersburg? Please clarify] and named after Bekhterev to evaluate the effectiveness of psychotherapy for psychosomatic disorders) [9] after completing four common stages of psychotherapy as criteria of psychotherapy effectiveness.

TREATMENT

The therapy involved similar drugs of the same cost (listed as medicines and medical products issued for free and on a preferential basis to the population as part of the guaranteed scope of free medical care at outpatient level for certain diseases, and specialised medical products with compensation coefficient of 1.0 in the Republic of Kazakhstan), administered according to the same dosage regimen. The regimen was based on the currently most common and recommended stepwise antihypertensive therapy: increasing the dosage to a maximum, with addition of further drugs in case of inefficiency (see Figure 1).

Treatment started with a diuretic with addition of a β-blocker. Further, if necessary, we added angiotensin-converting enzyme (ACE) inhibitors, Ca and imidazoline receptor agonists. The first step was low-dose thiazide diuretic indapa-

Figure 1. Dynamics of BP in different groups



Picture 1. Antihypertensive drugs dosage regimen.

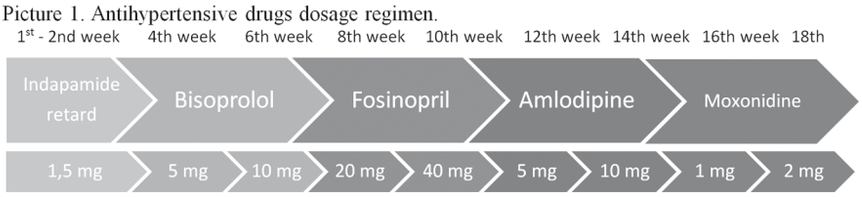


Table 1. Stages of the psychotherapeutic programme

Stage 1	Objectives	Establishing psychotherapeutic contact Setting goals
	Methods	Neurolinguistic programming Rational psychotherapy
Stage 2	Objectives	Treatment motivation Activation of personal resources Changing the system of patient's ideas and formation of responsibility
	Method	Short-term positive (focused) psychotherapy
Stage 3	Objectives	Influencing the psychological component of disease Potentiation of growth hormone treatment effect Normalisation of psychovegetative relations Correction of negative emotions
	Methods	Rational psychotherapy Symboldrama (katathym imaginative psychotherapy)
Stage 4	Objectives	Correction of internal disease pattern Psychotherapeutic work with psychological defences and secondary advantages by disease Developing adequate attitude to comprehensive supporting treatment Correction of associated neuropsychiatric disorders Support for independence and initiative of the patient
	Methods	Rational psychotherapy Neurolinguistic programming Gestalt therapy

mide retard 1.5mg; if that was non-effective, step 2 was add-on β-blocker bisoprolol 5mg; if that was non-effective then step 3 was to increase the dose of bisoprolol to 10mg, etc.

Psychotherapeutic work was carried out in a specially equipped room and comprised several stages (Table 1). Four stages were necessary for all patients of group 1 during the initial 6 weeks; after that patients who did not show convincing BP reduction were received to individual psychotherapy sessions. For individual sessions psychotherapists used the same methods (neurolinguistic programming, rational psychotherapy, short-term positive (focused) psychotherapy, symboldrama (katathym imaginative psychotherapy), Gestalt therapy). Sessions were held three times a week, lasting from 60 to 90 minutes.

The study was regulated by bioethical norms according to article 43 of the law "About health care system", 4 June 2003, followed by articles 178–181 of the Code of the Republic of Kazakhstan "About national health and the health care system", as well as international standards of good clinical practice. Student's t-tests were performed for the comparison of two mean values, using standard computer programs for statistical processing: Microsoft Excel 2010 and SPSS version 11.0. Comparisons and correlations were performed separately for systolic and diastolic BP and all Mini-Mult parameters. A probability value of $p<0.05$ was considered statistically significant.

RESULTS

Clinical characteristics of patients (Table 2) were not significantly different in the two groups.

Target BP was achieved in 100% of cases but different groups of patients required different numbers of sessions (Table 3).

For the patients of group 1 the initial blood pressure was 158.7±8.04/98.73±2.75mmHg. By the third visit (week 4), owing to indapamide monotherapy, 4 patients achieved the target BP level. Mean blood pressure was 155.6±6.0/94.7±4.1mmHg. The same week concluded two stages of psychotherapy. On week 4, after completing three stages of psychotherapy and due to the concurrent use of indapamide and bisoprolol 5mg, 18 patients achieved target BP; mean BP was 148.9±5.3/90.4±3.7mmHg. After 8 weeks of treatment with a combined maximum dose of bisoprolol and indapamide and at the end of the psychotherapy course, the mean BP fell to 142.3±6.1/84.5±4.2mmHg and 11 patients achieved target BP. At week 10, after a full course of therapy, 100% of patients achieved the required level of BP, with the average level reduced to 134.27±3.7/82.93±5.1mmHg.

Patients in group 2 had a similar pattern of drug therapy but did not receive any psychotherapy. The initial BP was 157.4±6.01/97.4±2.53mmHg. At week 4, target BP was achieved by 3 patients, which is similar to the results in the first group. Mean BP was 154.8±5.3/94.3±3.9mmHg. At week 6, another 13 patients have had their BP lowered to an acceptable value, with mean BP at 147.2±5.5/91.5±4.6mmHg. Mean BP at week 8 decreased to 144.32±5.0/88.74±4.1mmHg and 10 patients achieved the threshold. By week 10, mean BP dropped to 141.3±4.9/85.7±4.0mmHg, with 5 patients showing significant improve-

Table 2. Baseline demographical characteristics of participants

Sociodemographic characteristics	Group 1, N=40	Group 2, N=35
Age, mean (years)	48.5±3.69	47.5±4.2
Sex		
Men, n	20	17
Women, n	20	18
Illness duration, mean (months)	65.3±2.7	65.9±6.4
Blood pressure, mean (mmHg)		
Systolic	158.7±8.04	157.4±6.01
Diastolic	98.73±2.75	97.4±2.53

Table 3. Rate of BP achievement by groups

Visit	1, 2	3	4	5	6	7	8	Not achieved
Week	1, 2	4	6	8	10	12	12	
Psycho-therapy stage*	1–2	3	4					
Group 1 (N=40)	0	4 (10.00%)	18 (45.00%)	11 (27.50%)	7 (17.50%)	0 (0.00%)	0 (0.00%)	0
Group 2 (N=35)	0	3 (8.57%)	13 (37.14%)	10 (28.57%)	5 (14.29%)	3 (8.57%)	1 (2.86%)	0
Total	0	7 (9.33%)	31 (41.33%)	21 (28.00%)	12 (16.00%)	3 (4.0%)	1 (1.33%)	0

Note: Refers to the first group only

ment. However, without psychotherapeutic intervention to achieve further effect at the 12th week of treatment, an increase was needed in the ACE inhibitors dose to a maximum, which produced an effect in another 3 cases. Mean BP was then 139.6±4.4/84.32±4.9mmHg. At week 14, the addition of Ca channel blocker (amlodipine) 5mg allowed the remainder of patients in group 2 to achieve target BP. Mean blood pressure decreased to 137.33±3.9/83.81±4.3mmHg.

The control examination of mean BP at week 14 showed that in the first group the mean was 134.27±3.7/82.93±5.1mmHg, whereas in the second group it was 137.33±3.9/83.81±4.3mmHg (see Figure 1). On performing the t-test we discovered that there was a statistically significant difference between the final SBP in the two groups (p=0.032), but no such difference existed in the final DBP between the groups (p=0.198).

After the common four stages of psychotherapy sessions in group 1 patients, we noticed significant improvement (according to the Tukaev's test scale for clinical effectiveness of psychotherapy [9]) in 15 patients (37.5%), improvement in 22 (55%) and slight improvement in 3 patients (7.5%). No patient demonstrated absence of improvement, but 18 patients did not reach target BP; they started individual psychotherapy sessions. At the follow-up (week 24) all group 1 patients were tested with the Mini-Mult, which showed qualitative improvements on all scales.

To assess cost-effectiveness, we conducted a "cost-effectiveness" and "cost-utility" evaluation according to the formula CEA=DC/Ef, where DC – direct costs, and Ef – effectiveness. As effectiveness we calculated consumption per unit of lowering blood pressure in mmHg. In general, we considered only direct medical costs, such as the costs of pharmacotherapy and of consulting specialists. Since the study involved outpatients, direct non-medical expenses (patient meals, transport, attendants) were not considered. Given that all patients were able to work, the account indirect costs were also considered inappropriate.

At the control examination of blood pressure at week 24, the average pressure increased in both groups (134.57/83.72mmHg in group 1; 138.22/84.41mmHg in group 2), however, it remained stable within the target values.

After calculating the direct costs it was identified that group 1 required an average of 47.81USD expenditure, with the average number of visits to achieve the target blood pressure at 4.52 (over 7.05 weeks). Average expenses in group 2 were higher, namely 48.62USD, with an average number of visits at 6.11 or 7.97 weeks. The costs of SBP and DBP reduction per one unit were also lower in the first group compared with the second group. However, the target BP level was achieved faster in the first group, thus reducing the load on doctors and saving time resources (this should also reduce indirect costs, but as mentioned before we calculated direct costs only) (see Table 4 – *next page*).

DISCUSSION

The thesis that modern psychotherapeutic techniques can affect somatic indicators, not only mental disorders in somatic diseases, is

Table 4. Costs of pharmacotherapy, effectiveness

	Expenses per patient, on average (USD)	Dynamics		Achieving target BP		Costs of SBP reduction (USD/ mmHg)	Costs of DBP reductions (USD/ mmHg)
		SBP	DBP	Visits	Weeks		
Group 1 (N=40)	47.81	–24.15	–14.96	4.52	7.05	1.98	3.19
Group 2 (N=35)	48.62	–19.2	–13.04	6.11	7.97	2.53	3.73

Note: BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure

very old, but currently no strong epidemiological evidence exists for an association between stress and sustained hypertension. Linden et al screened 60 patients with essential hypertension for anxiety, depression and anger, after which a programme was designed for each patient based on his or her psychological risk factors. After 10 weeks of individualised psychophysiological treatment significant reductions in ambulatory systolic and diastolic blood pressure were observed [10].

In another study Dickinson et al, after an analysis of 25 trials, found that relaxation was associated with small, but statistically significant reductions in both systolic and diastolic blood pressure. However, they concluded that in view of the poor quality of included trials and unexplained variation between trials, the evidence in favour of causal association between relaxation and blood pressure reduction is weak [11].

In our study target BP in the psychotherapy group (group 1) was better and more stable (p=0.038 for SBP and p=0.198 for DBP). We associate the lack of statistically significant difference in final diastolic blood pressure between the two groups with less dynamic and less variable diastolic blood pressure values. Direct costs were lower in group 1 and the clinical effect was reached faster, but undoubtedly the study had several limitations.

LIMITATIONS

Therapy regimens implemented by cardiologists are very variable and largely depend on the individual case. Drugs can be priced differently and cause different side-effects that can alter the results of therapy. Finally, a group of psychosomatic disorders has heterogeneous responsiveness to the ongoing psychotherapeutic intervention and less stability. Economic calculations are relevant to the Republic of Kazakhstan, but will be different in another country with another type of the healthcare system. But we should not forget that after treatment with psychotherapy, the "emotional quality of life" in group 1 was better based on the Mini-mult test. Also, we should add that in Kazakhstan therapist and psychiatrist consultations at the primary care level are covered by the national healthcare system and entirely free of charge for patients.

From the perspective of the treatment process, focus must be made on the early detection of psychosomatic disorders and on referring the patient to the appropriate specialists, as this can not only help achieve stable clinical improvement, but also accelerate patient throughput, while reducing average costs.

Thus, based on the data presented here we can surmise that the use of a psychotherapeutic approach in a group of psychosomatic patients suffering from essential hypertension is justified from the clinical, organisational and economic perspectives.

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