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Pharmacological and Experimental Study of the Sedative Drug "Flegmen"

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Abstract

Background. Distress, due to pain, fear/anxiety, dyspnea, or delirium is common among critically ill patients. Distress may manifest clinically as agitation that is often associated with ventilator asynchrony and vital sign abnormalities. Regardless, distress needs to be treated to comfort the patient, ameliorate agitation that may interfere with supportive care, and attenuate increases in sympathetic tone, which may have untoward physiological effects. Purpose. Common sedative-analgesic medications used to treat distress in critically ill adults. Identifying the cause of distress and using this information to select the optimal sedative-analgesic agent is discussed separately. The aim of the study was to evaluate effectiveness of the new sedative drug complex “Flegmen” in preclinical study. Materials and Methods. The elemental composition of sedative assemblage "Flegmen" was analyzed by the method of mass spectrometry induction coupled plasma on the instrument ICP-MS 7500a AT the company "Agilent Technologies". Sedative assemblage "Flegmen" contains 39 elements. In the greatest number of macrocells in the sedative assemblage "Flegmen" contains chlorine, phosphorous, bromine, sodium, chromium, titanium, zinc and strontium. Also set the content of calcium (9.6 µg), which relieves the consequences of stress. Amino acid composition of sedative collection was studied analyzer. Identification of amino acids of the collection and their quantitative content in nanomolar was calculated according to the integrator, which is supplied with amino acid analyzer. Clinical studies were performed in the Republican Specialized Scientific-Practical Center (RSSPC) of Therapy and Medical Rehabilitation, the Department of Neurology, Departments of GP-therapy, Clinical Allergology, Propedeutics of Internal Diseases, Hematology, and Professional Diseases in the Tashkent Medical Academy. Experiments and Results. The study included 90 patients who received drug, which is studied, and 60 patients received the drug comparison on outpatient and inpatient care. Clinical study was divided three particular clinical trials. Patients were divided into two groups: basic and control. Mean age was 44.5±3.61 year. According to evaluation of the effectiveness of the drug "Flegmen" was found extremely tolerability in all 90 (100%) patients. Side effects were not revealed in the research. Conclusion. It was confirmed that sedative assemblage "Flegmen" is the most effective at treatment of patients with various diseases followed by an asteno-neurotic syndrome and neuroses that allows to recommend it for use in practical health care.

Keywords: Sedative combined tea «Flegmen», Clinical trials, Efficacy, Tolerance.

Contents

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1. Introduction

The integral development stage of the medicine (M) production is clinical studies during which the new preparation is studied for data acquisition about its efficiency and safety. It is very important that the market has only those drugs which completed all course of clinical tests and have authentic characteristics of efficiency, safety and economic expediency. The combined use of the medicinal plants (MP) in the form of plant collections allows to receive a synergism in operation and wider range of pharmacological action due to influence of each component that promotes increase of efficiency of phytotherapy. MP, which is a part of the assemblage, can correct medical action of each other. Assemblages are well combined with methods of treatment of official medicine, other medicines and with each other; they have soft impact on an organism, thus, the reached lasting medical effect possesses high efficiency. Due to this, the new structure of sedative assemblage - "Flegmen" has been developed [1].

The assemblage "Flegmen" is the multicomponent phytopreparation, which includes Regel plant – 30%, a motherwort grass – 30%, roots of a licorice - 20%, peppermint leaves - 20%. It is obvious that all components of assemblage are allowed for use in medicine, however in such composition they are applied for the first time. The medicine received from other plant of this sort favourably differs from a valeriana medicine in influence on cardiovascular system, the central sedative effect and diuretic effect. The preparation is recommended in conditions of hypererethism of CNS-neurosises, epilepsy, neurotic sleeplessness, and also as sedative means - at a hypertensive illness in combination with another calming and sedatives. By our researches it is revealed that tincture of a Regel also prolongs the sleep by geksenal for 84,7%, and chloral hydrate for 37,8%. The motherwort is a traditional demulcent and is widely applied in scientific medicine in the form of infusion, tinctures and other forms. The roots of licorice and peppermint leaves together with corrective properties, also have the calming effect on nervous system and are widely applied in various structures of collecting herbs. This assemblage is recommended to be applied at sleep disorders, the neurosis-like states, at somatic diseases, followed by irritability, nervousness, anxiety and sleep disorder [2, 3].

2. Experimental Part

The research included 90 patients who received the studied medicine, and 60 patients who received compared medicine while being on outpatient and inpatient treatment. Clinical trials were conducted in the Republican Specialized scientific and practical center of therapy and medical rehabilitation of MoH of RUZ in office of neurology, in departments of GP - therapy with clinical allergology and propaedeutics of internal diseases, hematology, the prof. of an illness of the Tashkent Medical Academy.

Criteria of inclusion in research were: the patients who are on outpatient and inpatient treatment of both sexes, aged more than 18 who gave the written informed consent to participate in research with diagnoses: 1) Astenisation of CNS; 2) Hypertensive illness of II and III degrees; 3) Astenizazation of CNS against the main pathology (hepatobiliary system, pathology of kidneys); 4) Asthenovegetative syndrome; 5) Neurocirculatory Dystonia.

Criteria of not inclusion in research: 1) Age of patients under 18; 2) Pregnancy; 3) Lactation; 4) Existence of hypersensibility to medicine components; 5) Patients with hypersensibility to components of a medicine and participating in other clinical trials during the last 30 days; 6) Absence of the informed written consent to participate in clinical trial.

The first clinical study were conducted in the Republican Specialized scientific and practical center of therapy and medical rehabilitation of MoH of RUZ in office of neurology *[The report of clinical trial. Study of sedative efficiency and tolerability of the medicine "Sedative assemblage — Flegmen".-Clinical base: RSSPMC of Medical rehabilitation Therapy of MoH RUZ. - 05.07.2011.]*.

The research included 30 patients who received the studied medicine, and 20 patients who received compared medicine while being on outpatient and inpatient treatment. Groups were comparable on sex, age and the diagnosis. Results of own researches showed that research included only 50 patients who were divided into two groups: the main and control. The main group included 17 women (56,6%) and 13 (43,3%) men, average age was 50,9±3,03 years. 13 (65%) men and 7 (35%) women were included in control group, average age was 44,5±2,09 years.

For comparison of results, received the "Sedative assemblage - Flegmen" in relation to the original indicators and the comparison group significance level (p) is set equal to 0.05 and 0.01. A value of p=0.01 is used here as estimation of the severity of action of the drug or different drug effects. The presence of significant differences in two values of the consequence level indicate the main effect of the drug or its contrast to the comparison drug.

Sedative assemblage "Flegmen" in the ratio of 1:10 was administered to the patients of the main group (30 people) 1/3 - 1/2 cup 2-3 times a day for 15 - 20 minutes before meals for 2-3 weeks on the background of basic therapy. Patients in the comparison group (20 people) took the drug Sedonik with similar effects. Drugs and other medicines were applied for the necessary treatment, compatible with the drug, as well as necessary physiotherapy treatments. Clinical examinations included monitoring the severity of complaints of patients, measurement of blood pressure and pulse, irritability, sleep disturbance. Tolerability was evaluated on the basis of subjective symptoms and sensations reported by the patient, and objective data obtained by the researcher in the treatment process. The dynamics of all indicators, the incidence and nature of adverse reactions requiring discontinuation of the drug, or permits administered, or rejection of the patient from further participation in the study were taken into account. In Table 1 is given the criteria of efficiency of the studied drug.

The analysis of efficiency of the research was conducted according to the scheme provided by the protocol.

In addition, in order to study the clinical effectiveness of assemblage "Flegmen", we performed analyses of complex clinical-biochemical studies. While studying the dynamics of blood parameters, i.e. initial and dynamics of treatment identified, such as hemoglobin, count of red and white blood cells, erythrocyte sedimentation rate in both groups.

Table-1. Criteria for evaluating the effectiveness of the trial drug.

4 points	High efficiency	Full clinical recovery by the end of the treatment course, disappearance of complaints and symptoms, heart rate, blood pressure, data from clinical examinations
3 points	Moderate efficiency	Significant reduction of complaints and symptoms (sum of scores 0-3 points) and clinical manifestations majority (71-85%) of the disease by the end of treatment, significant improvement in clinical examinations
2 points	Low efficiency	Slight reduction of complaints and symptoms (sum of scores 4-6 points) most of the clinical manifestations (40-60%) of the disease by the end of treatment, slight improvement of the data of clinical examinations
1 point	Lack of effectiveness	No change or worsening of clinical indicators by the end of the treatment.

Biochemical tests in main groups were carried out and found normal concentration of bilirubin, ALT and AST. Side effects of the sedative assemblage "Flegmen" were tested in the dynamics. When studying the data electro-encephalography, in most patients of both groups the original flat type EEG, and dysfunction trigger effect of specific midline structures, lower brain activity, etc. were revealed. After the tenth day course negative effects of drugs on these parameters was not identified.

Tolerability - trial drug was assessed on the basis of subjective symptoms and sensations reported by the patient, and objective data obtained by the researcher in the treatment process. Also, the dynamics of laboratory indicators and the incidence and nature of adverse reactions were taken into account. Table 2 shows the criteria for the tolerability of trial drug. Tolerability was assessed in points: in the analysis of any possible side effects, it is necessary to exclude side effects that may occur from taking other drugs or therapeutic treatments prescribed to the patient along with the test drug.

Criteria for evaluating the effectiveness of the trial drug were carried out:

1. The list of performance indicators.
2. Clinical improvement of the patient's condition.
3. Improving laboratory data.
4. Evaluation of effectiveness of trial drug was carried out on the basis of the above criteria with score according to the following scale:

Table-2. Criteria for assessing the tolerability of trial drug

4 points	very good (not observed adverse effects)
3 points	good (observed minor side effects that does not cause serious problems to the patient and does not require discontinuation of the drug)
2 points	satisfactory (there are side effects that affect the patient, but do not require discontinuation of the drug)
1 point	unsatisfactory (unwanted side effect of having a significant negative impact on the condition of the patient requiring discontinuation of the drug)
0 point	very poor (side effect requiring discontinuation of the drug and use of additional medical interventions)

During the evaluation of the effectiveness of the drug "Flegmen" very good tolerability in all 30 (100%) patients was found. Side effects were not revealed in the research.

Before the start of the study, patients complained on headaches, neurasthenia and neurotic reactions, accompanied by irritability, anxiety, insomnia, general weakness. The ten-day acceptance of assemblage contributed to the improvement of clinical case of patients that was manifested by a decrease or disappearance of irritability, nervousness, restlessness, and anxiety. Patients reported about improved sleep, improvement in mood and health. The results of the study showed that the use of sedative assemblage "Flegmen" in the treatment of patients with various diseases, such as nervous and cardiovascular system accompanied by sleep disturbances, irritability, anxiety, and insomnia did not have a special influence on blood pressure levels, heart rate.

A relative improvement of cerebral circulation in both groups was accompanied by subjective recovery health of patients, i.e. irritability and anxiety decreased and disappeared, and sleep was normalized. Generally, in the group which was receiving sedative assemblage "Flegmen", efficiency was 3.4±0.16 score, acceptance - approximately 4 score. In addition, in other group taking the drug "Sedonik", efficiency was 3.3±0.19 score, acceptance was also 4 points. When assessing the effectiveness of sedative assemblage "Flegmen, high efficacy was reported in 55% of patients, moderate efficiency in 30%, and low efficiency in 15 %. In the group of patients, who has taken "Sedonik", high efficiency of treatment was observed in 10 (50%) patients, moderate efficacy was in 5 (25%) patients, low efficiency was in 5 (25%) patients. Table 3 shows the results of the effectiveness and tolerability of sedative assemblage "Flegmen" and "Sedonik".

Table-3. The effectiveness and tolerability of the sedative assemblage "Flegmen" and "Sedonik"

Name of the drug	**Effectiveness**	**Tolerability**
Sedative collection "Flegmen"	3.4±0.16	4 points

Second clinical study was conducted at the Department of GP-therapy and Clinical Allergology. The main group of patients (consisted of 30 patients) received trial medication. Second group received the reference drug and there were 20 patients. The groups were matched by sex, age and diagnosis *(Report of a clinical study. Study of sedative efficiency and tolerability of the medicine "Sedative assemblage — Flegmen".-Clinical base: RSSPMC of Medical rehabilitation Therapy of MoH RUZ. - 05.07.2011.]*

The sedative assemblage "Flegmen" in the ratio of 1:10 was administered to the patients of the basic group (30 patient) 1/3 -1/2 cup 2-3 times a day for 15 to 20 minutes before meals for 2-3 weeks on the background of basic therapy. Patients in the comparison group (20 patient) were taking other sedatives in a similar way. Other drugs were excluded with similar effects. Drugs and other medicines, compatible with the drug, as well as the necessary physiotherapy treatments were applied for the necessary treatment. The list of clinical inspections consisted of: supervision over severity of complaints of patients, measurement of blood pressure and pulse, irritability, and sleep disorder.

The following clinical types of analysis were conducted:

1) General blood analysis, General urine analysis;
2) Biochemical tests: ALT, AST, bilirubin;
3) Instrumental studies: EEG.

Tolerability was evaluated on the basis of subjective symptoms and sensations reported by the patient, and objective data obtained by the researcher in the treatment process. Average rating of the tolerability and effectiveness in scores for the sedative assemblage "Flegmen" was 4 score, for other sedative drugs - also 4 score. In the control group a complete clinical recovery by the end of the treatment course, disappearance of complaints and symptoms, heart rate and blood pressure were reported. The results are presented in Table 4.

Table-4. The results of the effectiveness of "Flegmen" in second group of patients.

Figure	**Sedative assemblage "Flegmen"**		**Sedative drugs**	
	before	**after**	**Before**	**after**
Nervousness	1.8±0.22	0.0±0.00	1.9±0.08	0.0±0.00
Irritability	1.9±0.13	0.0±0.00	1.8±0.11	0.0±0.00
Sleep disturbance	1.8±0.02	0.1±0.07	1.7±0.17	0.0±0.00

Both drugs did not show side effects on general blood analysis, hepatic enzymes and bilirubin. The results are presented in Tables 5 and 6.

Table-5. The changes of the results of general blood analyses in second group of patients.

Figure	**Sedative assemblage "Flegmen"**		**Sedative drugs**	
	before	**after**	**Before**	**after**
Hemoglobin	119.6±2.23	119.7±2.09	121.0±3.29	121.5±3.27
Red blood cells	4.1±0.06	4.1±0,05	4.0±0.06	4.0±0.07
Leukocytes	5.7±0.23	5.6±0.26	5.6±0.31	5.6±0.3

Table-6. The results of changes in the indicators of hepatic enzymes and bilirubin in the second group of patients.

Figure	**Sedative assemblage "Flegmen"**		**Sedative drugs**	
	before	after	Before	After
ALT	0.3±0.02	0.3±0.02	0.4±0.02	0.3±0.02
AST	0.3±0.02	0.3±0.02	0.3±0.02	0.3±0.01
Bilirubin	13.5±0.73	13.5±0.71	12.6±0.75	12.6±0.61

During the test, there were not any factors that could contribute to the exclusion and cessation of the research with any of the patients. Thus, it was revealed that sedative assemblage "Flegmen" has sedative effect and has no other side effects. Consequently, sedative assemblage “Flegmen” is an effective sedative drug that has effects in patients as monotherapy or on a background of basic therapy.

Third clinical study was held in the Department of Internal Diseases, Hematology, and Professional Disease *(Report of a clinical study. Study of sedative efficacy and tolerability of the drug is "a Collection of sedative – Flegmen". - Clinical base: the Department of Internal Diseases, Hematology, MFT, Professional Disease.- 31.07.2012).*

Also main group consisted of 30 patients and they received the trial drug, second group of patients received comparator drug and the group included 20 patients. Each groups were matched by sex, age and diagnosis.

Patients of the basic group (30 people) were given the sedative assemblage "Flegmen" in the ratio of 1:10; 1/3 - 1/2 cup 2-3 times a day for 15 to 20 minutes before meals for 2-3 weeks on the background of basic therapy. Comparison group patients (20 people) received other sedatives in a similar way. Other drugs with similar effects were excluded. Drugs and other medicines were applied for necessary treatment, compatible with the drug, as well as the necessary physiotherapy treatments.

Clinical examination: observation of severity of complaints of patients, measurement of blood pressure and heart rate, nervousness, irritability, sleep disturbance.

The severity is evaluated in points according to the following scale:

0) None; 1) Minor; 2) Moderate; 3) Severe.

Clinical tests: 1) General blood analysis, General urine analysis; 2) Biochemical tests: ALT, AST, bilirubin; 3) Instrumental studies: EEG

- Clinical improvement in patient;
- Improvement of laboratory data.

The evaluation of the studied drug effectiveness was carried out on the basis of the above criteria according to the following scale (Table 7):

Table-7. Evaluation of the drug efficiency in scores

4 points	high efficiency	full clinical recovery by the end of the treatment course, disappearance of complaints and symptoms, heart rate, blood pressure, data from clinical examinations
3 points	moderate efficiency	Significant reduction of complaints and symptoms (sum of points 0 - 3 points) and clinical manifestations majority (71-85%) of the disease by the end of treatment, significant improvement in clinical examinations
2 points	low efficiency	Slight reduction of complaints and symptoms (sum of points 4-6 points), most of the clinical manifestations (40-60%) of the disease by the end of treatment, slight improvement of the data of clinical examinations
1 point	No efficiency	No change or worsening of clinical indicators by the end of treatment

Registration of the performance indicators was carried out immediately after inspection of research and/or receipt of the laboratory data. Information expressed in forms of quantitative indicators were subjected to statistical analysis, with the use of special software. The methods of variation statistics with the removal of the main parameters for the Student t-test were applied. Tolerability was assessed on the basis of subjective symptoms and sensations reported by the patient, and objective data obtained by the researcher in the treatment process. The dynamics of laboratory indicators and the incidence and nature of adverse reactions were taken into account. Tolerability was evaluated by using scores. Criteria of acceptability are presented in Table 8. Side effects and allergic reactions were not observed while receiving the sedative assemblage "Flegmen".

Table-8. The effectiveness of sedative assemblage "Flegmen" in third group of patients

Figure	**Sedative assemblage "Flegmen"**		**Sedative drugs**	
	Before	**After**	**before**	**after**
Nervousness	1.8±0.22	0.0±0.00	1.9±0.08	0.0±0.00
Irritability	1.9±0.13	0.0±0.00	1.8±0.11	0.0±0.00
Sleep disturbance	1.8±0.02	0.1±0.07	1.7±0.17	0.0±0.00

Tolerability: In the analysis of any possible side effects, it is necessary to exclude side effects that may occur from taking other drugs or therapeutic treatments prescribed to the patient along with the test drug.

For comparison of the results obtained from all control groups who were treated with “Flegmen” in relation to the original indicators and comparison group, the level of value (p) was set equal to 0.05 and 0.01. The value of p=0.01 was used in this case as an additional assessment of the severity of reaction of the drug or different drug effects. The presence of important differences at two values of the major level indicate a significant effect of the drug or its contrast to the comparison drug. Analysis of efficiency was conducted according to the results of study of patients, who received the drug according to scheme, were provided for this protocol. The results were shown in Table 4, 5, and 6. For collecting average rate of tolerability was eliminated with scores and sedative “Flegmen” was 3.9 score, other sedative drugs were also 4 score. Both drugs do not have side effects on general blood analysis, serum level of liver enzymes and bilirubin.

Changes of indicators of the general blood analysis while using the sedative assemblage "Flegmen" and other sedative drugs, have shown results that "before" and "after" the use of sedative assemblage "Flegmen" and other sedatives. Hemoglobin and red blood cells gave the same result as in Table 5. The substance of the leucocytes before treatment made 5.6±0.31 and after treatment - 5.5±0.3. Changes in the indices of liver enzymes of bilirubin with the use of sedative collection "Flagmen" and other sedatives gave results as in the Table 6.

When assessing mental status of patients, pathologic abnormalities were not identified. Patients both in the main and control groups complained about nervousness, irritability, sleep disturbance. After taking a sedative collection "Flegmen", improvement in overall health in 100% of patients, disappearance of irritability in 85%, nervousness in 75% and improved sleep in 70% of patients were noted. In the group with application of a baseline of conventional therapy was also noted improvement of the general condition of patients, reduced irritability and better sleep. For comparison of the results obtained from all control group treated with the assemblage, with respect to the initial parameters and the comparison group level of significance, the level of importance was set equal to 0.05 and 0.01. A value of p=0.01 is used here as estimation of the severity of action of the drug or different drug effects. The presence of difference in two values of the significance level indicate a significant effect of the drug or its contrast to the comparison drug. Studies for an individual patient can be terminated in the event of patient adverse reactions requiring discontinuation of the drug, or the ineffectiveness of the drug in this patient, or when skipping taking the drug, or when the refusal of a patient from further participation and research. In the latter case to explore should determine the motives for leaving to perform a final examination. The assessment can be stopped in the event of a serious adverse reaction in one patient or not serious adverse reactions in many patients, or effectiveness of the drug in a significant percentage of patient.

90 patients were examined. The main group included 90 patients who on the background of basic therapy, the drug "Flegmen" was given from 1 packet for 10 days to all patients. The average age of patients was 44.5±3.61 years. Analysis of the results of the patient’s clinical condition showed that in both groups systolic blood pressure (SBP), diastolic blood pressure (DBP) and heart rate remained within normal values before and after treatment in both study groups. Dynamics of blood parameters: pressure and heart rate were examined after receiving the drug "the sedative assemblage – Flegmen" produced by "SORB-TECH", Uzbekistan *(Report of a clinical study. Study of sedative efficacy and tolerability of the drug is "Collection of sedative – Flegmen". - Clinical base: RSNPC Therapy of medical rehabilitation Ministry of Health.- 20.04.2015.)*, basic average blood, such as hemoglobin, erythrocytes, and erythrocyte sedimentation rate were normal from the beginning. In the dynamics of treatment a relative trend to the increase in the content of erythrocytes, hemoglobin and leukocytes, and a certain tendency to decrease in the sedimentation rate and these numbers were within normal values were showed.

In the group of patients taking traditional basic therapy, a tendency to increase level of hemoglobin, leukocyte count and decrease in erythrocyte sedimentation rate were revealed, and also these changes were of doubtful character and stayed within normal values. The study of the dynamics of biochemical indicators baseline and after the application of sedative assemblage – "Flegmen" revealed that the level of ALT, AST and bilirubin remained within normal values.

In summary, the analysis of the obtained data testifies the positive dynamics of the clinical condition of patients in both groups. Negative impact of sedation on indicators of hemoglobin, erythrocytes, erythrocyte sedimentation rate and leukogram are not found. There are also no reliable oscillations of bilirubin, aminotransferases in the blood, which indicates the safety of the drug and the absence of negative hepatotropic effects. Side effects while the drug use were not found. The Table 9 presents a comparative evaluation of efficacy and tolerability of patients treated with sedative drug –"Flegmen" produced by "SORB-TECH", Uzbekistan, and patients taking traditional basic therapy.

Table-9. Comparative evaluation of efficacy and tolerability

Figure	Flegmen	Control group
Effectiveness, point	3.9±0.01	3.9±0.01
Tolerability, point	3.9±0.01	3.9±0.01

Clinical trials have shown that the use of the drug "sedative assemblage Flegmen" produced by "SORB-TEX", Uzbekistan, in the complex treatment of patients with syndrome of vegetative dystonia, improves clinical status, general well-being and disappearance of irritability, nervousness and improve sleep patients. The drug "sedative assemblage - Flegmen" is well tolerated by patients in clinical trials, adverse reactions were not identified. Sedative collection “Flegmen”, is an effective sedative drug, well tolerated, and fully compatible with other sedative drugs.

Further, the fact that this drug is developed by the Tashkent Pharmaceutics Medical Institute, it is allowed for clinical use and registered in the Republic of Uzbekistan, on the basis of positive clinical trial results from 3 clinical centers. Currently LLC “Sorb-tex” Uzbekistan plans to produce sedative collection “Flegmen” based on “guidance on conducting clinical trials and examination of materials” (order of the MOH of Republic of Uzbekistan No. 334, dated 25.07.2001) registration of the drug will be carried out on the basis of limited clinical trials.

3. Conclusion

Thus, based on the results of clinical trials, the drug "Flegmen" is a highly effective drug during all the specified indications. Clinical tests have proved positive clinical efficacy and tolerability of the "Flegmen" as a sedative. It was confirmed that the drug "Flegmen" is the most effective in the treatment of patients with various diseases accompanied with asthenic-neurotic syndrome and neurosis that can be recommended for use in practical health care.

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