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Original Article

Experimental and Clinical Studies on the Therapeutic Effects of Koryo Medicine-Rapid Coronary Blood Flow Enhancer Atherosclerosis and Some Ischemic Heart Diseases

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ABSTRACT

Background and Aim: Some Koryo medicines have a very positive effect on cardiovascular diseases such as arteriosclerosis, angina pectoris, myocardial infarction, and acute coronary syndrome by improving coronary blood flow and enhancing cardiac activity. The aim of this study was to investigate the experimental and clinical effects of Koryo medicines including *Carthami flos, Typhae pollen, Ligustici rhizoma, Salviae miltiorrhizae radix*, Veratri maximowiczii herba, Epimedii herba, Ginkgo folium, Crataegi fructus, Bupleuri radix, Astragali radix, ivy vine on several cardiovascular diseases. **Methods:** The composition of "rapid coronary blood flow enhancer": *Carthami flos* (powder) 0.2, Bupleuri radix (water extract) 0.15, *Ligustici rhizoma* (powder) 0.15, *Typhae pollen* (flour) 0.15, *Salviae miltiorrhizae radix* (water extract) 0.25, Astragali radix (water extract) 0.25, Veratri maximowiczii herba (water extract) 0.3, Crataegi fructus (powder) 0.3, ivy vine (water extract) 0.3, Epimedii herba (water extract) 0.1, Ginkgo folium (water extract) leaves 0.1 were mixed with honey and prepared by encapsulation to a weight of 0.5g. The experimental animals (Wistar rats) that developed the coronary atherosclerosis model were administered at a dose of 0.6g/kg once daily for 14 days and the experimental parameters were analyzed. Patients with angina pectoris, atherosclerosis, and hypertension were treated with 2 tablets at a time and 3 times a day for 25 days before eating. **Results:** In coronary atherosclerosis animals and clinical trials, HDL, SOD and CAT activities were significantly elevated, TC, TG, LDL, and LPO levels were significantly decreased ($p<0.001$), and electrocardiographic findings were significantly improved. **Conclusion:** The "rapid coronary blood flow enhancer" consisting of several Koryo medicines improves plasma lipids and antioxidant parameters and rapidly relieves clinical symptoms.

Keywords: Coronary artery, Coronary blood flow, Arteriosclerosis, Angina, *Carthami flos*, *Typhae pollen*.

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INTRODUCTION

Acute Coronary Syndrome (ACS) refers to Unstable Angina Pectoris (USAP), ST non-elevation myocardial infarction, and ST-elevation myocardial infarction with similar pathophysiology of coronary plaque.

Diseases involved in ACS are not heterogeneous, and they are caused by the common pathophysiological features: information of intracoronary acute thrombosis due to rupture and erosion of atherosclerotic plaques, and subsequent coronary incompleteness and complete occlusion, which are the major contributors to cardiovascular disease. Recently, it has been demonstrated that the acute complete or incomplete occlusion of the coronary artery due to rupture of the atherosclerotic plaque and the resulting thrombus is the main cause of ACS.[1]

The atherosclerotic plaque can be disrupted by the degree of autoinflammatory response, external physical stimulation, and in particular, the thin cap, the number of cells involved in the inflammatory response, the relatively large lipid core, and the low number of smooth muscle cells, which are associated with an increased risk of rupture, leading to unstable plaques.[2-5] After plaque rupture, complete occlusion of the coronary artery by thrombosis, which is formed by fibrin, platelets, and erythrocytes, is the cause of ST elevation acute myocardial infarction, and incomplete occlusion is the cause of unstable angina or ST non-elevation acute myocardial infarction.[6]

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Unstable angina or ST non-elevation acute myocardial infarction does not completely block blood flow and reduces blood flow, whereas ST-elevation acute myocardial infarction is associated with myocardial necrosis due to the formation of a small embolus caused by the rupture of plaque.[6,7]

The relationship between Superoxide Dismutase (SOD) and lipid peroxidation in atherosclerosis has been examined, and it has been reported that when complications such as hypertension, obesity, diabetes, infarction, and thrombosis are present, the change in SOD activity is less pronounced than in the absence of complications, but the level of Hydroperoxide Lipids (HLP), the primary product of lipid peroxidation, is markedly elevated.[8-10]

We evaluated serum levels of Myeloperoxidase (MPO) in patients with acute coronary syndrome, observed a significant increase in cardiac risk in patients with elevated MPO.

Coronary artery disease, considered to be the cause of ASC, is a heart disease that mainly underlies coronary atherosclerosis. Plaque sclerosis of the coronary artery leads to coronary stenosis and occlusion, resulting in coronary flow disturbances. This leads to cardiac lesions that result in a lack of myocardial blood supply, and clinical signs such as cardiac pain, heart rate abnormalities, further myocardial infarction, and myocardial weakness.[11,12]

Although coronary blood flow enhancers with certain therapeutic effects are marketed in most patients during acute attacks of coronary disease over the years, many coronary patients, especially those with chronic diabetic coronary disease, are already not well tolerated and even doubled doses are not effective. Myocardial ischemia is the cause of coronary artery disease. Therefore, coronary arteries are stenosed or plaque formation, which may result in hematologic disturbances or myocardial infarction. This condition can only be drug-dependent and can be sustained, yet there is no complete treatment, and even worse. Only cardiac bypass surgery can be performed, which is only a temporary treatment. Adverse effects of synthetic drugs occur at a higher rate compared to traditional Koryo medicine. Therefore, there is a marked increase in demand for Koryo medicines in the market.

Under these circumstances, the development of Koryo medicines for rapid coronary flow improvement is urgent; the development of Koryo medicines for the alleviation of symptoms such as myocardial ischemia, angina, myocardial infarction, and other by increasing coronary flow is becoming important. This study presents a small number of experimental and clinical trials on the impact of the new "rapid coronary flow enhancer" with herbal medicine upon biochemical marker changes of angina pectoris, some symptoms of angina and atherosclerosis, and blood pressure changes in hypertension.

MATERIALS AND METHODS

Experimental Animals

The experimental protocol was approved by the Scientific Review Committee of Haeju College of Medical Sciences. Wistar rats (150-200 g body weight, 25 males and 20 females) were breed under standard environmental conditions [22±2°C, 60-70% humidity, 12 hr light/dark cycle (from 7:00 a.m. to 7:00 p.m.)]. Water was allowed to take freely and standard experimental diets were given once a day at 8 a.m. All animals were acclimatized to the environment for 7 days before the experiment.

Formulation and Preparation of Koryo Medicines

Formulation of Koryo medicines: *Carthami flos* (powder) 0.2, Bupleuri radix (water extract) 0.15, Ligustici rhizome (powder) 0.15, *Typhae pollen* (flour) 0.15, *Salviae miltiorrhizae radix* (water extract) 0.25, *Astragali radix* (water extract) 0.25, *Veratri maximowiczii* herba (water extract) 0.3, Crataegi fructus (powder) 0.3, ivy vine (water extract) 0.3, Epimedii herba (water extract) 0.1, Ginkgo folium (water extract) leaves 0.1.

Preparation of Koryo medicines

The *Carthami flos, Ligustici rhizoma, Typhae pollen*, Crataegi fructus were pulverized and passed through sieve No. 100 (medicine-1).

Water extracts were prepared at 100°C for Bupleuri radix, *Salviae miltiorrhizae radix*, Astragali radix, Veratri maximowiczii herba, ivy vine, Ginkgo folium and were prepared at 60°C for the Epimedii herba (medicine-2).

The medicine-1 and medicine-2 were mixed and kneaded with honey to prepare the capsule with a weight of 0.5 g.

Experimental Model and Application of Koyo Medicines

Experimental model

Rats were sensitized by subcutaneous injection of 0.3 mL of 1% Bovine Serum Albumin (BSA, Sigma) at 3-day intervals, and then 0.5 mL of BSA was injected into the femoral vein 7 days after the last injection to develop allergic subangiitis. From 7 days before challenge to 7 days after challenge, high-fat diets (cholesterol 1.5%, pig oil 0.25%, bile acid 0.25%) were mixed with standard diets (98%) and modeled by natural intake.

Application of Koryo medicines

From day 1 to 14 after challenge, the "rapid coronary blood flow enhancer" was mixed with the diet at a dose of 0.3 g/kg to allow natural intake once a day. The study was divided into groups 1 (normal group), 2 (model group) and (Koryo medicines administered to model group).

Experimental Parameters Measurement

Seven days after challenge, rats were sacrificed by carotid artery dissection, blood samples were collected, serum was isolated, TC, TG, HDL-c, LDL-c, and LPO were measured, and erythrocyte SOD and CAT were measured and compared with the control group.

Clinical Study Procedures

In healthy subjects and patients before and after medication, the ECG was performed, venous blood was collected after overnight fasting (minimum 12 hr), and TC, TG, HDL-c, LDL-c, LPO, CPK, AST, and LDH, erythrocyte SOD, CAT, were measured and compared.

Drug Administration

Patients were given "rapid coronary blood flow enhancer" two tablets at a time, three times before meals for 25 days.

Statistical Analysis of Data

Data were analyzed using SPSS software (version 22.0; IBM Corp., Armonk, NY, USA). Data were expressed as Mean±Standard Deviation (SD) or median (interquartile range). Comparisons among the three groups (normal, model, and Koryo medicine groups) were performed using one-way Analysis of Variance (ANOVA) followed by the Tukey *post-hoc* test for pairwise comparisons. Categorical variables, such as ECG findings, were analyzed using the chi-square test or Fisher's exact test wherever appropriate. A P value < 0.05 was considered statistically significant.

RESULTS

As a preliminary step for large-scale clinical trials, clinical trials were conducted under small-scale conditions based on animal data. A clinical study was conducted at the South Hwanghae Provincial General Hospital and the Koryo Hospital in South Hwanghae Province of the DPRK.108 subjects were included in the study, including angina pectoris (n=42) and relatively healthy individuals (n=18), and were divided into the group of Koryo medicine treatment and control group. Other hypertensive diseases (n=23) and atherosclerosis (n=25) were examined for their antihypertensive and antiarrhythmic effects and for their anti-palsy effects on limb. The general characteristics of the study population are as follows (Table 1).

Table 2 shows the changes in serum lipid parameters (TC, TG, HDL-c, LDL-c, LPO) and antioxidant enzymes (SOD, CAT) in the normal, control and Koryo medicine groups. When the coronary atherosclerotic rats in the control group were compared with the normal group, TC, TG, LDL-c and LPO were significantly increased, and the activities of antioxidant enzymes and HDL-c content were significantly decreased (P<0.001). The Koryo medicine group that received oral "rapid coronary flow enhancer" at a dose of 0.3 g/kg for 14 days after challenge injection significantly reduced TC, TG, LDL-c and LPO, and significantly increased the activities of antioxidant enzymes and HDL-c content (p<0.001) compared with the control group. Since there is no destruction of myocardial tissue in experimental coronary atherosclerosis, myocardial enzymes have not been examined.

Table 3 shows the serum lipid parameters (TC, TG, HDL-c, LDL-c, and LPO), myocardial enzymes (LDH, CPK, AST), antioxidant enzymes (SOD, CAT), and ECG changes (ST elevation, Infarct Q wave) in healthy and angina patients (control group, Koryo medicine group). Compared with healthy subjects, patients with angina without Koryo medicine had significantly increased TC, TG, LDL-c, and LPO, and significantly decreased the activities of antioxidant enzymes and HDL-c (p<0.001). Activity of the myocardial enzymes LDH, CPK and AST did not show a significant increase in patients with angina pectoris compared with healthy subjects.

The "rapid coronary blood flow enhancer" was administered to patients with angina pectoris, two tablets at a time, three times before meals for 25 days. When administered the Koryo medicine to angina patients, TC, TG, LDL-c, and LPO were significantly lower, and the activities of antioxidant enzymes and HDL-c were significantly increased (p< 0.001) compared to patients without Koryo medicine. When myocardial cells were damaged, the activities of blood-derived enzymes LDH, CPK and AST in myocardial tissue did not change when compared to controls. In the presence of ECG changes, only one of 20 patients (5%) had ST elevation and Infarct Q waves, while the application of a traditional Koryo medicine did not show ECG abnormalities.

The effects of the treatment of cardiac pain, scapular radiating pain, and epigastric pain in patients with angina have been shown to be 95.2% (40/42) when used for 25 days, starting 3 days after the administration of the Koryo medicine. In hypertensive patients, blood pressure decreased by an average of 30-40 mmHg after approximately 1 hr of single administration of a Koryo medicine, and arrhythmia disappeared after about 20 min, resulting in normal pulse. Patients with atherosclerosis in limb had weakness of palsy on limb after 3 to 5 days of Koryo medicine. After 7-10 days, all patients had a marked improvement in their symptoms and increased their appetite due to the increased blood circulation of the digestive system.

DISCUSSION

Coronary heart disease is mainly coronary atherosclerotic heart disease. Coronary atherosclerosis predisposes to coronary stenosis, occlusion, resulting in coronary flow disturbances, even with cardiac symptoms such as myocardial blood supply deficiency, angina, heart rate loss, myocardial infarction, and cardiac contractility loss. As seen in many years of practice, it is clearly established that the coronary blood flow enhancer marketed in the market has some alleviation in most patients

during the acute attack of coronary heart disease. Myocardial ischemia is the cause of coronary heart disease. Coronary stenosis causes blood flow obstruction, angina pectoris, and myocardial infarction, which leads to coronary heart disease. This condition can only be drug-dependent and survive, and without radical therapy, the disease is progressively worse. Only cardiac bypass surgery can solve the problem for the time being.

Synthetic medicine has stronger side effects than traditional Koryo medicine. Koryo medicines have a significant therapeutic effect in coronary heart disease. The main drug of the "rapid coronary blood flow enhancer" is *Carthami flos*, affecting the heart and liver, which makes blood circulation good, lowering blood pressure and relieving pain.

Since the *Carthami flos* has mild cardiac stimulation and acts to increase coronary blood flow by decreasing coronary artery occlusion, it has some degree of myocardial ischemia improvement, myocardial infarction treatment, and arrhythmia treatment, and also normalizes menstrual disorder. Therefore, it is recommended for amenorrhea, postpartum abdominal pain, swelling, and coronary blood circulation disorders.[13,14] *Typhae pollen* acts on the liver, heart, and spleen to stop bleeding, to allow good blood flow and to allow good urine retention. Thus, it is used for uterine bleeding, postpartum abdominal pain, angina pectoris, hyperlipidemia, eczema, etc.[15-17] *Ligustici rhizoma* acts on the liver and gallbladder to make blood pass, relieve wind, relieve pain, and normalize menstruation. Thus, *Ligustici rhizoma* helps the effect of *Carthami flos*, and is used for amenorrhea, hypertension, neurasthenia, insomnia, postpartum abdominal pain, etc.

Salviae miltiorrhizae radix acts on the heart to help the circulation, normalize menstrual cycles, relieve pus, cause new flesh and relieve pain, Therefore, it is used for menstrual disorders, amenorrhea. insomnia, angina, hepatitis, cerebral thrombosis, hypertension, etc. Astragali radix acts on the heart, spleen, lungs, and nerves, stopping sweat, causing good urine, draining pus, and surviving flesh, so that it is frail, chronic gastritis, chronic hepatitis, coronary circulatory disorders, cerebral anemia, swelling, edema, nephritis, etc.

Crataegi fructus acts on the spleen, gastrointestinal tract, helps digestion, helps blood flow, and helps appetite, causing dyspepsia, early hypertension, hyperlipidemia, atherosclerosis, neurasthenia, arrhythmia, and coronary circulatory disorders. Epimedii herba is strong tendon and bone, so it is used by the impotence, tinnitus, amnesia, dysmenorrhea, and weak person. Ginkgo folium are used for atherosclerosis and hyperlipidemia as lipid-lowering agents and vasodilators, and for heart ischemia, myocardial infarction, angina pectoris due to coronary blood circulation disorders, and limb pain due to cerebral arteriosclerosis. Veratri maximowiczii herba is used for diuresis, biliary secretion, and lipid-lowering effects, including hepatitis, cirrhosis, coronary atherosclerosis, and hypertension. Bupleuri radix is used for menstrual disorders, hepatitis, cholecystitis, and hyperlipidemia, which affect the liver, gallbladder, and heart.

Anthocyanins of ivy fruits are potent antioxidants and diuretics, which have beneficial effects on the heart, liver and urinary system. The "rapid coronary flow enhancer" was prepared using the 12 herbal medicines mentioned above, which treat the

Table 1: General characteristics of the study population.

General characteristics of patients	n=108
Age, Mean±SD	66.3±15.6
Gender	
Men (n, %)	80 (74.1)
Women (n, %)	28 (25.9)
Body mass index (kg/m^2), mean±SD	27.31±3.52
Angina pectoris, n (%)	42 (38.9)
Hypertensive disease, n (%)	23 (21.3)
Atherosclerosis, n (%)	25 (23.1)
Clinical symptoms	
Chest pain and radiating pain, n (%)	40 (44.4)
Breathlessness, n (%)	32 (35.5)
Palpitation of chest, n (%)	35 (38.9)
Nausea, n (%)	20 (22.2)
Palsy on limb, n (%)	20 (22.2)
Dizziness disease, n (%)	18 (20)
Arrhythmia, n (%)	30 (33.3)
Weak out, n (%)	85 (94.4)
Temperature rise, n (%)	15 (16.7)
Current smoke, n (%)	75 (83.3)
Alcohol use, n (%)	68 (75.5)
Examination findings	
Systolic blood pressure [mmHg (a)]	192.9±14.5
Diastolic blood pressure [mmHg (a)]	154.8±22.9
ST elevation, n (%)	1 (1.1)
Infarct Q waves, n (%)	1 (1.1)
AST, n (%)	0 (0)
Leukocytosis, n (%)	1 (1.1)
Increased ESR, n (%)	1 (1.1)
Increased LDH, n (%)	0 (0)
TC (mg/dL), mean±SD (b)	194±13.5
HDL-c (mg/dL), mean±SD (b)	31.6±6.7
LDL-c (mg/dL), mean±SD (b)	185.2±24.7
TG (mg/dL), mean±SD (b)	94.9±11.4

(a): Hypertensive disease; (b): Angina pectoris; AST: Aspartate transferase; ESR: Erythrocyte sedimentation rate; LDH: Lactate dehydrogenase; TC: Total cholesterol; HDL-c: High density lipoprotein-cholesterol; LDL-c: Low density lipoprotein-cholesterol; TG: Triglyceride.

Table 2: Lipid parameters and levels of antioxidant enzymes in normal and experimental coronary atherosclerosis and in the group of rats administered Koryo medicines.

Experimental index	Normal group (n=10)	Control group (n=10)	Koryo medicine group (n=10)	P value △
Lipid profile				
TC (mg/dL)	109.5 (90-122)	128.5 (106-152)**	114.1 (94-138)	0.0364
TG (mg/dL)	87.1 (70-105)	104.5 (90-131)**	93.1 (78-108)	0.0406
HDL-c (mg/dL)	35.3 (25-51)	22.3 (11-38)*	30.7 (20-41)	0.0379
LDL-c (mg/dL)	130.1 (100-160)	210.9 (150-247)**	185.4 (154-211)	0.0277
LPO (nmol/mL)	0.82 (0.5-1)	2.42 (1.5-3.2)**	1.95 (1.6-2.2)	0.0194
Antioxidative enzymes				
SOD (U)	5.5 (4.8-6.3)	3.1 (2.1-5.1)**	4.5 (3.5-5.2)	0.0014
CAT (μmol/min/mg)	11.2 (10-12.3)	7.5 (5.2-9.8)**	9.2 (6.4-11.1)	0.0223

* Comparison of Group I (normal group) and Group II (control group); △Comparison of experimental group 2 (control group) with group 3 (Koryo medicine group), Frequency is expressed as %; TC: Total cholesterol; TG: Triglyceride; HDL-c: High density lipoprotein-cholesterol; LDL-c: Low density lipoprotein-cholesterol; LPO: Lipid peroxide; SOD: Superoxide dismutase; CAT: Catalase.

Table 3: Lipid parameters, diagnostic marker enzymes, levels of antioxidant enzymes, and ECG findings in normal, control and Chinese medicine groups.

Experimental index	Normal group (n=18)	Angina pectoris		P value △
		Control group (n=17)	Koryo medicine group (n=25)	
Lipid values				
TC (mg/dL)	124.1(110-135)	202.1(172-213)**	188.6(152-208)	0.0023
TG (mg/dL)	73.4(52-88)	101.6(86-123)**	90.3(66-107)	0.0028
HDL-c (mg/dL)	40.0(30-48)	26.9(14-38)**	34.7(26-41)	0.0009
LDL-c (mg/dL)	137.7(109-164)	199.7(156-243)**	175.3(150-218)	0.0010
LPO (nmol/mL)	1.1(0.8-1.7)	2.8(2-3.8)**	2.4(1.9-3)	0.0059
Diagnostic maker enzymes				
LDH (U/L)	25.6(20-31)	27.8(20-38)	25.8(21-32)	0.1054
CPK (μmol/h)	132.3(120-140)	137.5(130-148)	136.3(125-142)	0.4562
AST (μmol/h)	93.2(80-109)	97.4(80-112)	95.3(80-111)	0.5007
Antioxidative enzymes				
SOD (U)	5.8(4.8-7)	3.9(2.9-5.1)**	4.4(3.4-6)	0.0306
CAT (μmol/min/mg)	13.9(10.6-18.4)	8.9(5.2-13.5)**	10.9(6.4-14.1)	0.0034
ECG				
ST elevation, cases/incidence	18/0 (0)	20/1 (5)	22/0 (0)	
Infarct Q waves, cases/incidence	18/0 (0)	20/1 (5)	22/0 (0)	

TC: Total cholesterol; TG: Triglyceride; HDL-c: High density lipoprotein-cholesterol; LDL-c: Low density lipoprotein-cholesterol; LPO: Lipid peroxide; LDH: Lactate dehydrogenase; CPK: Creatine phosphokinase; AST: Aspartate transferase; SOD: Superoxide dismutase; CAT: Catalase. * Comparison of Group I (normal group) and Group II (control group), △Comparison of experimental group 2 (control group) with group 3 (Koryo medicine group). Frequency is expressed as percentage.

symptoms of angina and myocardial infarction due to coronary atherosclerosis and myocardial ischemia, has no side effects, has rapid therapeutic action and has high therapeutic effect. In particular, hypertension (ischemia-related hypertension) has a very rapid antihypertensive and antiarrhythmic effect: blood pressure decreases from 1 h after the first dose of koryo medicine, blood pressure stabilizes when 7 to 10 days are used, arrhythmias disappear with one dose, and most symptoms of hypertension, angina, and atherosclerosis are healed completely after 25 to 30 days of use. It is also safe to use because there are no side effects even with a long duration of 1-2 months.

Of course, acute onset angina or myocardial infarction should be treated with nitroglycerin and used with traditional Koryo medicine.

On the other hand, because of its potent antioxidative and peripheral vasodilatory effects, "rapid coronary flow enhancer" has positive therapeutic effects not only on cardiac disease but also on sexual dysfunction, gastrointestinal, pulmonary and neurological diseases, which need further investigation.

CONCLUSION

In this study, we present a small number of experimental and clinical trials on the biochemical marker changes of angina pectoris, some symptoms of atherosclerosis, and its effect on blood pressure changes in hypertension, in order to provide a basis for a large-scale clinical trial of the newly developed "rapid coronary flow enhancer" with traditional Koryo medicine. Further large-scale clinical trials will be needed.

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ABBREVIATIONS

ACS: Acute Coronary Syndrome; **USAP:** Unstable Angina Pectoris; **STEMI:** ST-Elevation Myocardial Infarction; **NSTEMI:** Non-ST-Elevation Myocardial Infarction; **BSA:** Bovine Serum Albumin; **TC:** Total Cholesterol; **TG:** Triglycerides; **HDL-c:** High-Density Lipoprotein Cholesterol; **LDL-c:** Low-Density Lipoprotein Cholesterol; **LPO:** Lipid Peroxide Lipid Peroxidation Products; **SOD:** Superoxide Dismutase; **CAT:** Catalase; **CPK:** Creatine Phosphokinase; **AST:** Aspartate Aminotransferase; **LDH:** Lactate Dehydrogenase; **ECG:** Electrocardiogram; **HLP:** Hydroperoxide Lipid.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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