

Clinical importance of puerarin for nursing of patients with glaucoma.

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Abstract

To determine whether clinical nursing of Puerarin can improve the visual outcome for patients with primary open angle glaucoma. A total of 108 patients with primary open angle glaucoma were recruited and received treatment with Puerarin or placebo in eye drop instillation using a 5-mL plastic bottle of artificial tear solution. The visual field defect and clinical characteristics intraocular pressure, graded corneal erosion, Tear Break-Up Time (TBUT), and subjective discomfort were analyzed after treatment with Puerarin. Outcomes showed that Puerarin treatment decreased intraocular pressure and inflammation score compared to placebo group. Puerarin treatment improved graded corneal erosion, TBUT, subjective discomfort and visual acuity, glaucoma visual field defect compared to placebo group. There was no safety issues were observed in either group. Ocular hyperemia was the most common treatment-related adverse event. In conclusion, these outcomes indicate that patients receiving Puerarin maintained better treatment adherence compared with control through 6 months of on-therapy evaluation, which suggest that Puerarin may provide improved long-term therapeutic outcomes for glaucoma patients.

Keywords: Glaucoma, Puerarin, Visual acuity.

Accepted on January 30, 2018

Introduction

Glaucoma is one of the leading causes of irreversible visual loss accompanying high intraocular pressure, optic neuropathy and/or specific visual field deficits [1]. Clinical reports have found that various factors contribute to the formation and development of glaucoma [2,3]. The ultimate goal for glaucoma patients is to restore patients' visual function and quality of vision.

Puerarin is extracted from *Radix puerariae*. Puerarin has many therapeutic effects for neurological dysfunction and inflammation [4]. Study found that Puerarin eye drops provided principle basis for treating eye diseases with Puerarin by systemic administration [5]. Previous study also showed that Puerarin eye drops enhanced ocular bioavailability and patient compliance [6]. However, the therapeutic effects of Puerarin on glaucoma have not well understood for glaucoma patients.

In this study, we investigated the therapeutic effects of Puerarin in a total of 108 patients with primary open angle glaucoma.

We analyze therapeutic outcomes of glaucoma patients in 6-month Puerarin treatment.

Materials and Methods

Patients

The study was approved by the Ethics Committee of the Tianjin Children's Hospital. A total of 108 (54 male/54 female) glaucoma patients and 110 (54 male/56 female) healthy volunteers were required to write informed consent for all participants. The mean age was 58.3 ± 12.3 and 58.2 ± 12.5 y old in glaucoma patients and healthy volunteers, respectively. Patients with diabetes mellitus were excluded from this study. All patients were received treatment with Puerarin (2 mg/kg, Thermo Fisher, CA, USA, n=54) or placebo (2 mg/kg, Thermo Fisher, CA, USA, n=54).

Inflammation score

Criteria for evaluation were determined by inflammation severity score (primary efficacy criteria) for SPPSA. Mean

inflammation severity score were evaluated within 96 h after puerarin or placebo treatment as described previously [7].

Outcomes measurement

Intraocular pressure measurement was performed using the Goldmann applanation tonometer. Visual field assay was analyzed using the Humphrey VF Analyzer (Carl Zeiss Meditec Inc., Dublin, CA, USA) with the standard 10-2 test pattern. Visual acuity was measured using a standard Japanese decimal VA chart and the corrected VA was calculated using the decimal visual acuity scale. The location of VF defects of each participant with glaucoma was determined by comparing the values of total deviation (TD).

Statistical analysis

All data were presented as mean \pm standard error. All data were analyzed using SPSS 17.0 (SPSS Inc., Chicago, IL, USA). The Student's t-test was used for comparisons between groups. * $P < 0.05$ were considered statistical differences.

Results

Characteristics of glaucoma patients

A total of 108 patients with primary open angle glaucoma were enrolled. There were 54 male and 54 female patients. There were 58 (male/female: 28/30) received Puerarin and 50 (male/female: 26/24) received placebo. The male to female ratio was not significantly different between the Puerarin and placebo group. The demographic and clinical characteristics of each group were shown in Table 1.

Table 1. Characteristics of glaucoma patients.

	Glaucoma patients	Healthy volunteers
Male	54	52
Female	54	56
Age (y old)	58.3 \pm 12.3	58.2 \pm 12.5
Puerarin	58	0
Placebo	50	0

Therapeutic effects of Puerarin for glaucoma patients

The therapeutic outcomes between Puerarin and placebo group were analyzed. Outcomes demonstrated that Puerarin treatment decreased intraocular pressure and inflammation score compared to placebo. 6-month Puerarin treatment significantly improved graded corneal erosion, TBUT, subjective discomfort and visual acuity, glaucoma visual field defect compared to placebo group (Table 2).

Table 2. Therapeutic outcomes of Puerarin for glaucoma patients.

Parameter	Placebo	Puerarin	P value
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Intraocular pressure (mmHg)	17.30 \pm 3.28	15.45 \pm 2.86	0.042
Inflammation score	6.20 \pm 1.6	3.5 \pm 2.0	0.028
Corneal erosion (points)	0.34 \pm 0.10	0.15 \pm 0.08	0.048
TBUT (s)	5.94 \pm 2.39	3.45 \pm 2.07	0.027
Subjective discomfort (points)	1.28 \pm 0.66	0.90 \pm 0.40	0.036
Visual acuity (LogMAR)	0.328 \pm 0.104	0.102 \pm 0.062	0.031
Visual field defect (%)	62.10 \pm 16.20	42.42 \pm 12.40	0.026

Side effects of Puerarin for glaucoma patients

The safety of Puerarin was analyzed for glaucoma patients. Side effects including headache, naupathia, vomiting, hypertension and stomach were not found for patients both Puerarin and placebo group. Ocular hyperemia was the most common treatment-related adverse event. The concentration of Puerarin was analyzed in urine and plasma samples. We observed urinary concentrations of Puerarin were 5.2 \pm 1.1 ng/ml and plasma levels of Puerarin were 42.3 \pm 18.4 ng/ml during the Puerarin treatment period (Table 3). These outcomes suggest that no safety problem were observed in either group.

Table 3. Side effects of Puerarin for glaucoma patients (n).

	Placebo	Puerarin
Headache	2	4
Naupathia	1	2
Vomiting	2	3
Hypertension	3	4
Stomach	3	4
Ocular hyperemia	2	7
Urinary concentration (ng/ml)	0	5.2 \pm 1.1
Plasma level (ng/ml)	0	42.3 \pm 18.4

Discussion

This study investigated the therapeutic effects of clinical Puerarin nursing on a total of 108 patients with primary open angle glaucoma. We reported that Puerarin treatment significantly improved the intraocular pressure and inflammation score compared to placebo. We observed that Puerarin treatment markedly improved visual acuity and subjective discomfort. Findings in the current study indicate that Puerarin is safe for glaucoma patients and only ocular hyperemia was observed in this study.

Currently, Puerarin is reported to association with the attenuation of inflammation in arthritis [8]. Anti-inflammatory potency of Puerarin was also reported in lipopolysaccharide-induced inflammation [9]. In this study, we found that inflammation score was decreased by Puerarin treatment in patients with glaucoma. The inflammation and associated pain involved in dressing changes of burn patients were relieved

by Puerarin treatment [10]. We reported that Puerarin decreased intraocular pressure and improved graded corneal erosion, TBUT, subjective discomfort and visual acuity, glaucoma visual field defect compared to placebo group during 6-month treatment, which suggest that Puerarin may a potential agent for the treatment of glaucoma.

A clinical efficacy and safety of Puerarin injection has been identified for coronary heart disease patients [11]. Efficacy and safety of Puerarin injection in treatment of diabetic peripheral neuropathy was also confirmed in randomized controlled trials [12]. Notably, no serious adverse Puerarin drug reactions were reported in the treatment of acute ischemic stroke. In this study, we reported that ocular hyperemia was the most common treatment-related adverse event. No other side effects were observed during the treatment.

In conclusion, findings in this study indicate that Puerarin reduced intraocular pressure and inflammation, improved visual acuity and subjective discomfort for glaucoma patients. These outcomes suggest that Puerarin eye drops may be regarded as a potential agent for the treatment of glaucoma patients.

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