

## Effect of Qingxue Dan on obesity and metabolic biomarker: a double-blind randomized-controlled pilot study

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### Abstract

**OBJECTIVE:** To investigate the clinical effect of Qingxue Dan (QXD) on obesity and metabolic biomarker related to obesity.

**METHODS:** A randomized, double blinded, placebo-controlled trial with a paralleled study design was conducted. Twenty-six obese volunteers aged between 30 and 60 with obesity and more than 2 metabolic risk factors were recruited at the department of oriental rehabilitation medicine, Kyung-hee university oriental medical hospital, Seoul, Korea. Subjects were randomly assigned to an intervention (QXD) group or a placebo group, and treated with 900 mg/d of QXD or placebo medicine for 8 weeks. Primary endpoint was the change of body mass index (BMI) at 8 week from baseline. Secondary outcomes included the change of body composition, abdominal fat mass measured with Dual energy X-ray absorptiometry (DXA), blood pressure, lipid profiles and the homeostasis model assessment for insulin resistance (HOMA-IR).

**RESULTS:** BMI was decreased in the QXD group sig-

nificantly. Total body fat, abdominal fat mass measured with DXA Region of Interest and waist circumference (WC) showed a trend toward decreasing in the QXD group, but fat free mass was decreased in all groups. Triglyceride (TG) was decreased in QXD group significantly, but WC, total cholesterol and high-density lipoprotein cholesterol were increased in both group. BP didn't change during the study period. HOMA-IR is decreased in both groups without group effect.

**CONCLUSION:** 8-weeks of oral administrations of QXD (900 mg/d) reduces BMI, with a tendency of lose of total body fat mass, especially abdominal fat. It also significantly reduced serum TG level. These results suggest QXD could be used to treat obesity and metabolic risk factors. Further study is needed to confirm our pilot findings.

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**Key words:** Qingxue Dan; Obesity; Hypertension; Hyperlipidemias; Insulin resistance; Randomized controlled trail

### INTRODUCTION

Obesity, particularly visceral obesity is the most common cause of insulin resistance, dyslipidemia and long-term vascular complications.<sup>1,2</sup> Although the cause of the syndrome remains obscure, visceral obesity was considered as central factor.<sup>3,4</sup>

Qingxue Dan (QXD) is a herbal formula consisting of Radix of *Scutellaria baicalensis* Georgi, Rhizoma of *Coptis japonica* Makino, Cortex of *Phellodendron amurense* Ruprecht, Fructus of *Gardenia jasminoides* Ellis, and Rhizoma of *Rheum palmatum* Linne. An

anti-hyperlipidemic activity,<sup>5,6</sup> anti-hypertensive activity,<sup>7</sup> anti-inflammatory actions,<sup>8</sup> and anti-atherogenic effects<sup>9,10</sup> of QXD have been proved so far. A previous study showed therapeutic effects of QXD on mice model of obesity and metabolic syndrome.<sup>11</sup> In the current study, we hypothesized that QXD will reduce body fat and improve other metabolic biomarkers in a clinical population of patients with obesity and metabolic risk factors.

## MATERIALS AND METHODS

### Study design

This randomized, double-blind, placebo-controlled clinical study was conducted at Kyung Hee University Oriental Medical Hospital from June 2009 to October 2009.

All procedures were carried out according to Declaration of Helsinki guidelines. The study protocol was approved by the Institutional Review Board consent form of the Medical Research Institute, Kyung Hee Medical Center, Seoul, Korea (komcirb 2009-09).

### Subjects

Subjects aged 30-60 years with obesity [body mass index (BMI)  $\geq 25$ ] who had more than 2 metabolic risk factors according to the criteria of the International Diabetes Federation (IDF) were recruited for this pilot study (Table 1).

The exclusion criteria included eating disorder, smoking, a potentially confounding medical condition (e.g. liver disease, renal disease, heart disease, thyroid dis-

ease, anemia etc.), taking medications that might affect body weight and metabolism within last 3 months (oral contraceptives or hormonal medications etc.), pregnancy or plan to pregnant, and breast feeding woman who has weight changes during recent 3 months. Subjects were recruited by newspaper and Internet advertisement. Participants had to give both verbal and written information regarding the study. Signed informed consent was obtained prior to entry.

### Materials

QXD (Code number: HH333) was obtained from Kyung Hee University Oriental Medical center (Seoul, Korea). QXD is a capsulated extract (300 mg per one capsule) of *Scutellariae Radix*, *Coptidis Rhizoma*, *Phellodendri Cortex*, *Gardeniae Fructus* and *Rhei Rhizoma* (Table 2). Each herbal medicine was extracted with 80% ethanol in boiling water for 2 h. These extracts were filtered and evaporated in a rotary vacuum evaporator and then finally lyophilized with a freezing dryer. To standardize the quality of QXD, berberine in *Coptidis Rhizoma* and *Phellodendri Cortex*, baicalin in *Scutellariae Radix* were quantitatively measured with high performance liquid chromatography (HPLC) as an index component (Figure 1).<sup>12</sup>

The placebo capsules were made with phenylthiocarbamide (PTC), squid ink, herbal flavor and starch, having similar organoleptic properties including weight, taste, color, odor and feel.

### Randomization and treatment

Subject was randomly assigned to the treatment group or placebo group using a computer random number generator with SAS 9.2 software. The clinical trial phar-

Table 1 IDF Criteria for metabolic syndrome (central obesity + 2 criteria)

Item	Risk factors	Defining level
Abdominal Obesity (Waist circumference)	Men	>90 cm or ethnicity specific
	Women	>80 cm or ethnicity specific
	Triglyceride	$\geq 150$ mg/dL (1.7 mmol/L)
HDL-cholesterol	Men	<40 mg/dL (1.03 mmol/L)
	Women	<50 mg/dL (1.29 mmol/L)
	Blood pressure	$\geq 130/85$ mm Hg
	Fasting blood glucose	$\geq 100$ mg/dL (5.6 mmol/L)

Notes: IDF: international diabetes federation; HDL: high density lipoprotein.

Table 2 Composition of QXD

Constitute herb	Scientific name	Weight (g)
Scutellariae Radix	Scutellaria baicalensis GEORGI (from Korea)	0.28
Coptidis Rhizoma	Coptis japonica MAKINO (from Korea)	0.28
Phellodendri Cortex	Phellodendron Amurense RUPRECHT (from Korea)	0.28
Gardeniae Fructus	Gardenia jasminoides ELLIS (from korea)	0.28
Rhei Rhizoma	Rheum palmatum L. (from korea)	0.07
Total		1.2

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