

## Efficacy and safety of *Citrus sudachi* peel in obese adults: A randomized, double-blind, pilot study

Masashi Akaike<sup>1</sup>, Ken-ichi Aihara<sup>2</sup>, Hiroaki Yanagawa<sup>3</sup>, Takashi Iwase<sup>4</sup>, Sumiko Yoshida<sup>2</sup>, Chiho Sato<sup>3</sup>, Tomoka Saijo<sup>3</sup>, Hiroaki Mikasa<sup>5</sup>, Yoshizaki Kashiwada<sup>6</sup>, Yoshihisa Takaishi<sup>6</sup>, Koichiro Tsuchiya<sup>7</sup>, Toshiaki Tamaki<sup>8</sup>, Toshio Matsumoto<sup>2</sup>, Masataka Sata<sup>4</sup>

<sup>1</sup>Department of Medical Education, <sup>2</sup>Department of Medicine and Bioregulatory Sciences, <sup>4</sup>Department of Cardiovascular Medicine, <sup>6</sup>Department of Natural Medicines, <sup>7</sup>Department of Medical Pharmacology, <sup>8</sup>Department of Pharmacology, The University of Tokushima Graduate School of Medical Sciences, <sup>3</sup>Clinical Trial Center for Developmental Therapeutics, Tokushima University Hospital, <sup>5</sup>Support Center for Medical Education, School of Medicine, The University of Tokushima, 3-18-15, Kuramoto-cho, Tokushima 770-8503, Japan

**Correspondence author:** Masashi Akaike, MD, PhD, Department of Medical Education, University of Tokushima Graduate School of Medical Sciences, 3-18-15 Kuramoto-cho, Tokushima 770-8503, Japan

Submission date: May 9, 2014; Acceptance date: June 27, 2014; Publication date: July 1, 2014

### **ABSTRACT**

**Objective:** This study was undertaken to explore the efficacy and safety of *Citrus sudachi* peel for metabolic risk factors in obese male and female adults.

**Background:** *Citrus sudachi* Hort. ex Shirai (Rutaceae), called “sudachi”, is a small, round, green citrus fruit that is mainly cultivated in Tokushima Prefecture in Japan. Our group reported that *Citrus sudachi* peel powder improved glucose tolerance and dyslipidemia in Zucker-fatty rats and reduced hyperglycemia and hypertriglyceridemia in GK diabetic rats.

**Materials and Methods:** We conducted a randomized, double-blind, placebo-controlled trial in 40 participants with abdominal obesity and metabolic risk factors including hypertension, impaired glucose tolerance and elevated triglyceride levels. Participants were randomized to receive either tablets that contained 1.3 g dried *Citrus sudachi* peel powder or placebo tablets for 12 weeks. The sudachi peel group included 14 males and 5 females with a mean age of 54.5 years, and the placebo group included 18 males and 2 females with a mean age of 51.9 years.

**Results:** Physical status including body weight, waist circumference and blood pressure and laboratory markers including metabolic parameters were not different at any observation point between the two groups. However, among participants with serum triglyceride levels of more

than 120 mg/dl, body weight, waist circumference and serum triglyceride levels were significantly decreased at several observation points after the start of treatment in the sudachi peel group but not in the placebo group. No serious adverse events were observed in the sudachi peel group.

**Conclusions:** *Citrus sudachi* peel has the potential effect to safely improve abdominal obesity and lower serum levels of TG in obese individuals with hypertriglyceridemia. A large-scale randomized, double-blind clinical study targeting subjects with both abdominal obesity and high TG levels is needed to confirm the metabolic effects of *Citrus sudachi* peel.

**Trial registration:** UMIN Clinical Trials Registry (UMIN-CTR) UMIN000002682. Accession number of the Ethics Committee for Clinical Trials of Food in Tokushima University Hospital is F5.

**Key words:** health functional food, anti-obesity, triglyceride