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**File: ■ Turmeric (*Curcuma longa*, Zingiberaceae)  
■ Nigella (*Nigella sativa*, Ranunculaceae)  
■ Metabolic Syndrome**

**HC 061536-533**

**Date: November 30, 2015**

**RE: Turmeric/Nigella Combination Improves Metabolic Syndrome Parameters**

Amin F, Islam N, Anila N, Gilani AH. Clinical efficacy of the co-administration of turmeric and black seeds (Kalongi) in metabolic syndrome – a double blind randomized controlled trial – TAK-MetS trial. *Complement Ther Med.* 2015;23(2):165-174.

Metabolic syndrome (MetS) is characterized by abdominal obesity and the co-occurrence of at least 3 of the following: high blood pressure (BP), elevated fasting blood glucose (FBG), high serum triglyceride (TG) levels, and low concentrations of high-density lipoprotein cholesterol (HDL-C). Medicinal plants may be used along with exercise and dietary modification to treat and prevent MetS as they contain bioactive phytochemicals with diverse metabolic effects. Experimental and clinical studies have shown that turmeric (*Curcuma longa*, Zingiberaceae) rhizome and nigella (*Nigella sativa*, Ranunculaceae) seed have hypolipidemic, hypoglycemic, and antioxidant effects. These authors followed up their 2014 study<sup>1</sup> showing the synergistic effects of these herbs by conducting a randomized, double-blind, placebo-controlled, clinical trial to evaluate the effect of these herbs alone and in combination among patients with MetS.

Patients were recruited from "a small community, Hijrat Colony, an urban-slum located at Mai-Kolachi, Karachi, Pakistan." Male residents of the colony with a waist circumference (WC) >90 cm (35.4 inches), along with 3 or more features of MetS, and who were not on regular medications were recruited. The exclusion criteria were as follows: hypertension or coronary heart disease; taking herbal supplements; on medications for hyperlipidemia, obesity, or chronic disease; and debilitation. The sample size was calculated for a 5% level of significance and a power of 80%. Assuming a 20% non-participation rate, at least 62 patients in each group were required.

A total of 250 patients (mean age, 44 ± 13.3 years) were randomly assigned to receive 1 of the following treatments daily for 8 weeks:

- 1.5 g powdered nigella (3 capsules of 500 mg each) (n = 62)
- 2.4 g powdered turmeric (3 capsules of 800 mg each) (n = 63)
- 900 mg nigella and 1.5 g turmeric (3 capsules, each containing 300 mg of nigella and 500 mg of turmeric) (n = 62)

- 1.5 g powdered psyllium (*Plantago ovata*, Plantaginaceae) seed husk (3 capsules of 500 mg each) (n = 63)

The selected dosage of the interventions was based on data from other studies. The source of the plant powders and their phytochemical characteristics were not reported. The patients visited the research site weekly to receive more capsules; compliance and adverse effects were also queried at each visit. In addition, compliance and adverse effects were monitored weekly by drug diary, phone calls, and bi-weekly visits by research officers in case of no contact. The patients were given education on lifestyle modifications to prevent and manage MetS at baseline and at 4 and 8 weeks.

At baseline and at the end of the study, the patients completed diet and physical activity questionnaires. Blood samples were drawn at baseline and after 4 and 8 weeks; they were analyzed to determine plasma levels of FBG, C-reactive protein (CRP), cholesterol, low-density lipoprotein cholesterol (LDL-C), HDL-C, and TGs. BP, WC, hip circumference (HC), and body mass index (BMI) were assessed at baseline and every 2 weeks.

At baseline, there were no significant differences among the groups in clinical characteristics. There were 6-9 withdrawals in each group. One patient in the nigella group quit due to nausea and 1 patient in the combination group dropped out due to excessive weakness, while in the turmeric group, 3 patients withdrew due to nausea and 1 due to skin pruritus (itching).

Compared to baseline, BMI, body fat percentage, and BP improved in all groups, but there were no significant differences among the groups. The authors attributed these improvements to lifestyle modifications.

After 8 weeks, TGs (P=0.001), cholesterol (P=0.02), FBG (P=0.02), LDL-C (P<0.001), and HDL-C (P=0.02) were significantly improved in the nigella group compared with placebo; however, when compared with baseline values, only cholesterol (P<0.001) and TGs (P<0.001) were significantly improved.

Compared with placebo, turmeric alone was more effective in reducing total cholesterol (P=0.009), LDL-C (P<0.001), and CRP (P<0.001), but had no significant effect on blood glucose. However, the effect on lipids was not significant compared to baseline.

In the combination group, improvements were observed in all clinical parameters compared with baseline values. Compared with the placebo group, greater improvements were seen in CRP (P=0.007), body fat percentage (P=0.04), total cholesterol (P=0.02), FBG (P<0.001), TGs (P=0.03), LDL-C (P<0.001), and HDL-C (P=0.04). Compared with the nigella group, the combination group showed greater improvements in HC (P=0.001), body fat percentage (P=0.008), weight (P<0.001), TGs (P=0.02), and CRP (P<0.001).

Although the occurrence of mild adverse effects was the highest in the turmeric group, there was no significant difference among groups. One patient in the nigella group and 3 patients in the turmeric group reported nausea, but there were no reports of nausea in the combination group. The authors suggest that this may be due to the lower dose of turmeric in the combination or the presence of nigella in the combination.

In summary, nigella alone improved lipid profiles and FBG and turmeric alone reduced LDL-C and CRP levels compared to placebo. However, the combination of nigella and turmeric (at 60% lower doses) improved several MetS parameters; the combination reduced body fat percentage, FBG, CRP, and improved lipid profiles. The study is limited by the failure to characterize the botanicals. These results need to be confirmed in longer-duration studies of larger and more ethnically diverse populations using herbs that have been chemically profiled.

—*Shari Henson*

**Reference**

<sup>1</sup>Amin F, Gilani AH, Mehmood MH, Siddiqui BS, Khatoon N. Coadministration of black seeds and turmeric shows enhanced efficacy in preventing metabolic syndrome in fructose-fed rats. *J Cardiovasc Pharmacol.* 2015;65(2):176-183.

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