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Does supplementation with green tea extract improve acne in post-adolescent women? A randomized, double-blind, and placebo-controlled clinical trial☆

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ABSTRACT

Background: Green tea is believed to have beneficial effects in the prevention and treatment of acne.
Objective: To examine the effects of a decaffeinated green tea extract (GTE), providing a daily dose of 856 mg of epigallocatechin gallate (EGCG) upon women with post-adolescent acne.
Methods: A randomized, double-blind, placebo-controlled clinical trial was conducted from May 2012 through October 2013. A final group of 80 subjects were randomly assigned to receive either 1500 mg of decaffeinated GTE or placebo (cellulose) daily for 4 weeks. Inflammatory lesion counts were used as the major outcome measurement. At baseline and after 4 weeks of treatment, anthropometric measurements, fasting glucose levels and a lipid profile were measured from both groups.
Results: Sixty-four of 80 women, from 25 to 45 years of age with moderate-to-severe acne completed the study. Statistically significant differences were noted in inflammatory lesion counts distributed on the nose, periorally and on the chin between the two groups. However, there were no significant differences between groups for total lesion counts. Within-group comparison revealed that the GTE group had significant reductions in inflammatory lesions distributed on the forehead and cheek, and significant reductions in total lesion counts. GTE resulted in significant reductions in total cholesterol levels within the GTE group.
Conclusions: GTE resulted in significant reductions in lesions located on the nose, perioral area and chin. More research is required to determine whether a decaffeinated GTE standardized for EGCG content will provide clinical benefits in women with post-adolescent acne.

1. Introduction

A subset of adult women have acne primarily involving the face, and many have unsuccessfully undergone standard acne treatments.[1] During the past decade, four major pathological processes have been found to play a critical role in the development of adult-onset acne: (1) increased sebum production by the sebaceous glands, (2) altered keratinization of follicular keratinocytes, (3) activity of *Propionibacterium acnes (P. acnes)*, and (4) inflammation.[2–4]

Epigallocatechin-3-gallate (EGCG), the major polyphenol in green tea, has potent anticarcinogenic, anti-inflammatory, and antimicrobial activities.[5–7] EGCG can modulate several key pathological factors of acne, including hyperseborrhea, lipogenesis, inflammation, and *P. acnes* overgrowth.[8–11] The efficacy of a lotion made with green tea extract was recently reported in clinical trials of acne patients.[11–14]

These observations led us to hypothesize that EGCG may be beneficial in women with post-adolescent acne. Therefore, we provide a daily dose of 856 mg of epigallocatechin gallate (EGCG) to examine the effects of a decaffeinated green tea extract (GTE) on women with post-adolescent acne.

☆ The trial was conducted at Branch of Linsen and Chinese Medicine, Taipei City Hospital; address: No. 145, Zhengzhou Rd., Datong Dist., Taipei, Taiwan.

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2. Materials and methods

2.1. Study design and participants

The trial was conducted from May 2012 through October 2013 at Taipei Hospital, Taiwan. A final group of 118 subjects met the inclusion-exclusion criteria. Enrolled subjects included women between 25 and 45 years of age, with moderate or severe acne vulgaris as defined by the Investigator's Global Assessment (IGA; score of 3 or 4 on a scale from 0 to 5).[15] None of the women had received systemic retinoid or hormone treatment during the previous 3 months. Subjects with systemic illness or dermatologic conditions that could interfere with treatment or evaluation were excluded from the trial. A total of 80 subjects enrolled in the study after providing written informed consent. The study protocol was approved by the Human Ethics Committee of Taipei Hospital. Patients were randomly allocated to receive a decaffeinated GTE (Group A) or a placebo (cellulose; Group B) for four weeks (Fig. 1).

2.2. Randomization and blinding

Subjects were randomized in a 1:1 ratio by a designated assistant (using a computed randomization list that generated treatment numbers in two groups) to receive either decaffeinated GTE or placebo. The randomization list and the electronic file were kept in a locked cabinet and in an electronic file with access restricted access to the designated personnel directly responsible for labelling and handling the study medications. These precautions were followed until the study database was locked and ready to be unblinded for statistical analyses. The investigators could not gain access to the randomization list, and the integrity of the blinding was ensured by packaging the product in identical opaque capsules and requiring a research assistant blinded to the product contents to dispense the capsules.

2.3. Preparation of samples and treatment

Decaffeinated GTE was obtained from the Tea Research and Extension Station, Taoyuan County, Taiwan. The GTE was extracted from dried leaves of green tea according to pre-set standard procedures, and was verified with a certificate of analysis. The decaffeinated GTE used in this study was standardized for several tea catechins in addition to EGCG (Table 1). The placebo was comprised of pure microcrystalline cellulose. Capsules contained either 500 mg decaffeinated GTE extract or cellulose. The subjects were asked to take 1 capsule 30 min after meals 3 times daily for 4 weeks. The total daily dosage of tea compounds received by the GTE treatment group is listed in Table 1.

Table 1
Components of decaffeinated GTE capsules and daily dose (in mg).

Components	% in Weight	Daily dose (in mg)	Per capsule (in mg)
EGCG (Epigallocatechin gallate)	57.12	856.8	285.6
ECG (Epicatechin gallate)	15.74	236.1	78.7
EGC (Epigallocatechin)	7.70	115.5	38.5
EC (Epicatechin)	4.80	71.9	24
GCG (Gallocatechin gallate)	4.25	63.7	21.25
GC (Gallocatechin)	<0.07	<1.05	<0.3
Caffeine	<0.07	<1.05	<0.3
Cellulose	10.33	155.0	51.65

2.4. Outcome measurements

Lesion counts were recorded by a blinded dermatologist for the entire face by counting each inflammatory lesion (papules, pustules, nodules, and cysts) and non-inflammatory lesion (comedones). Because we specified patient group by IGA score,[15] so the main outcome measure was the acne lesion counts.

At baseline and after 4 weeks of treatment, the following were assessed for both groups: body mass index (BMI, body weight in kilograms divided by height in meters squared, or kg/m^2), blood pressure (BP, mm Hg), waist circumference (WC), and hip circumference (HC). In addition, fasting glucose, triglycerides, high- and low-density cholesterol (HDL and LDL) levels were measured for both groups. In addition, the subject's quality of life was assessed using a Cardiff Acne Disability Index (CADI) questionnaire administered at each visit. The secondary outcome were lipid profile,[16,17] including triglycerides, total cholesterol, high- and low-density

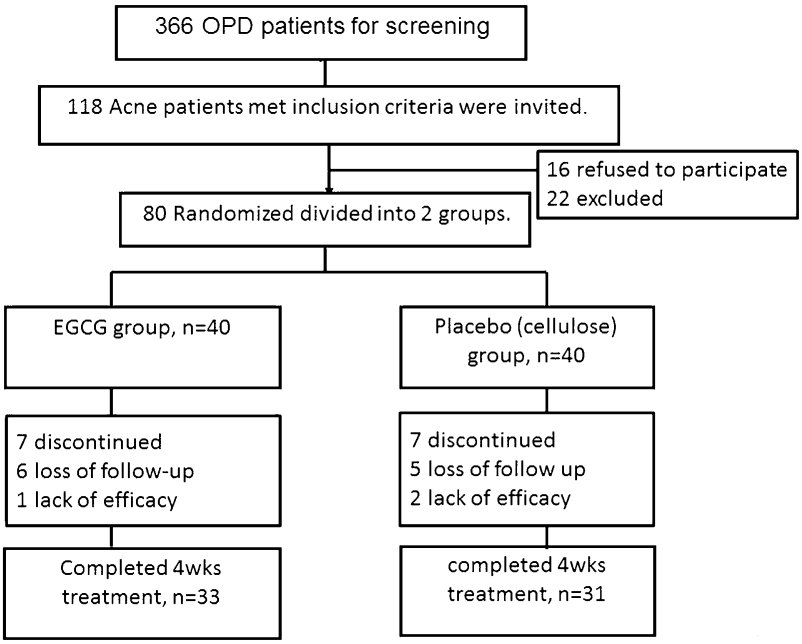

Fig. 1. Study Flow Diaphragm.