

## A NEW NUTRACEUTICAL WITH CITRUS BERGAMIA AND CYNARA CARDUNCULUS IMPROVES ENDOTHELIAL FUNCTION IN NON- DIABETIC INDIVIDUALS WITH LIVER STEATOSIS

*Elisa Mazza<sup>1</sup>, Roberta Pujia<sup>1</sup>, Yvelise Ferro<sup>2</sup>, Samantha Maurotti<sup>1</sup>, Tiziana Montalcini<sup>3</sup>  
Arturo Pujia<sup>1</sup>*

<sup>1</sup>Department of Health Science, University Magna Grecia, Catanzaro, Italy;

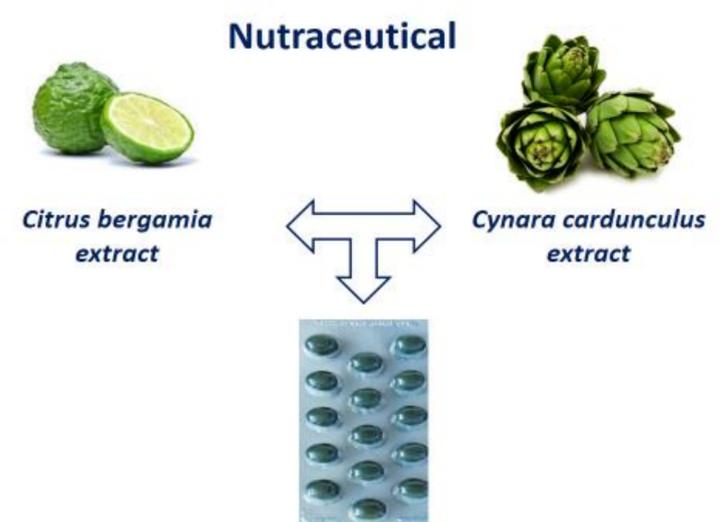
<sup>2</sup>Department of Medical and Surgical Science, University Magna Grecia, Catanzaro, Italy;

<sup>3</sup>Department of Clinical and Experimental Medicine, University Magna Grecia, Catanzaro, Italy.

**Background:** Non-alcoholic fatty liver disease (NAFLD) is the most common chronic liver disease in the world. Evidences suggest that NAFLD is associated with endothelial dysfunction and increases the risk of cardiovascular events. Endothelial dysfunction marks an early stage of atherosclerosis and is an important prognostic marker for cardiovascular disease (CVD). Reactive hyperemia peripheral arterial tonometry (RH-PAT) is a non-invasive, quantitative method useful to measure endothelial dysfunction. This method offers a digital measurement of hyperemic response (reactive hyperemia index, RHI). RHI score is inversely correlated with CVD. In a recent randomized clinical trial, we found that bergamot polyphenolic fraction (BPF) in combination with Cynara cardunculus (CyC) is able to reduce hepatic fat content in non-diabetic patients with NAFLD. The purpose of this study was to evaluate the effect of this nutraceutical on endothelial function in individuals with NAFLD.

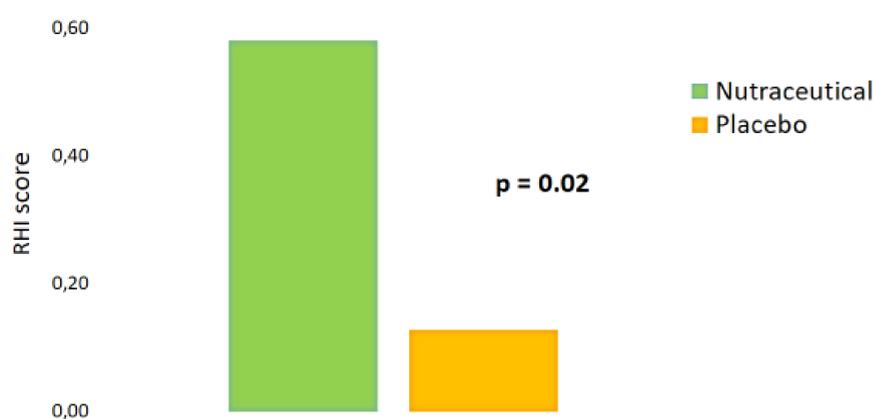
**Materials and methods:** We examined the data from 32 non-diabetic patients with NAFLD and endothelial dysfunction (RHI score  $\leq 1.67$ ) enrolled in a clinical trial (ID ISRCTN12833814) carried out at the University of Catanzaro from February to June 2019.

Sixteen individuals received one capsules daily of a nutraceutical containing 150 mg of BPF, 150 mg of CyC and 300 mg of albedo fibers micronized for 12 weeks. The intervention group was matched for age, gender and body weight to 16 individuals that received one capsule daily of placebo (600 mg maltodextrin). RHI score, by EndoPAT 2000 technique, liver fat content, by transient elastography, serum transaminases, lipids, glucose and insulin were measured at the baseline and the end of the study.

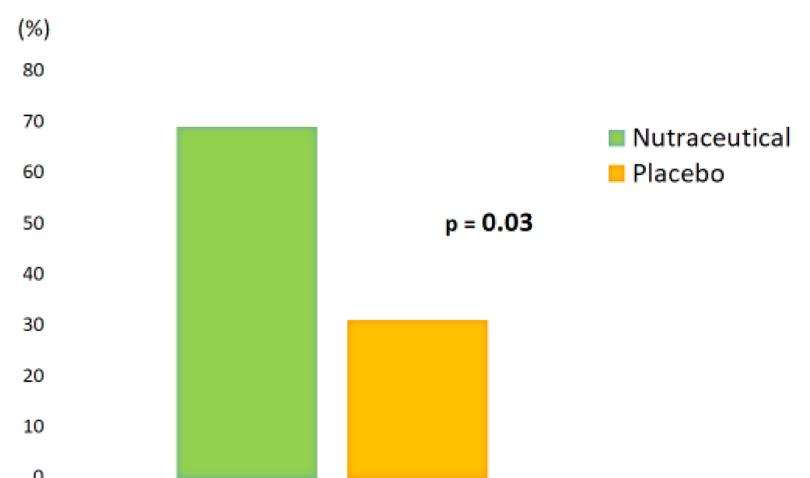


**Results:** A total of 69% were male. The mean age was  $52 \pm 9$  years, mean BMI was  $29.3 \pm 3$  kg/m<sup>2</sup> and RHI score was  $1.15 \pm 0.4$ . The overall frequency of dyslipidemia was 44% and hypertension was 34%. After 12 weeks, we found a greater RHI score increase in the participants taking the nutraceutical rather than placebo ( $0.58 \pm 0.5$  vs  $0.13 \pm 0.5$ ;  $p = 0.02$ ; +95% vs +30%). In intervention group, we also found a greater reduction in liver fat content than placebo group (69% vs 31%,  $p = 0.03$ ). There were no significant differences in the change of body weight, blood pressure, glucose, insulin, lipids and serum transaminases values between two groups after 12 weeks. A relationship between the liver steatosis reduction and improvement of endothelial function was not found.

Variation of Reactive hyperemia index according to the treatments



Liver fat content reduction according to the treatments



**Conclusions:** Current data show that a nutraceutical containing BPF and CyC, in addition to reducing hepatic fat content, improves endothelial function in non-diabetic subjects with NAFLD and, thus, could become an effective strategy for the prevention of CVD risk in subjects with liver steatosis.