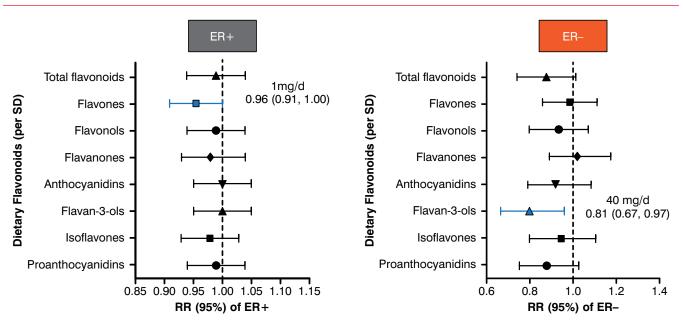
CLINICAL TRIAL HIGHLIGHTS





ER=estrogen receptor; SD=standard deviation.

The increments are 220 mg/d for total flavonoids, 10 mg/d for anthocyanidins, 40 mg/d for flavan-3-ols, 20 mg/d for flavanones, 1 mg/d for flavones, 10 mg/d for flavonols, 3 mg/d for isoflavones, and 170 mg/d for proanthocyanidins.

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plant-based diets have a protective role against breast cancer. Future pooled analyses of large cohort studies are warranted to confirm these findings.

Vegetable Oil Can Improve High-Density Lipoprotein Function

Written by Brian Hoyle

Researchers from Canada and the United States have shown that diets low in saturated fatty acids and high in unsaturated fatty acids, including monounsaturated and polyunsaturated fatty acids, all similarly reduce high-density lipoprotein cholesterol (HDL-C), which is associated with reduced obesity by boosting the efflux of cholesterol. The findings were presented by Xiaoran Liu, PhD candidate, Pennsylvania State University, University Park, Pennsylvania, USA.

HDL-C concentration has been inversely associated with the risk of cardiovascular disease in epidemiologic studies. But this relationship has not been evident in clinical trials, suggesting that HDL-C function, rather than concentration, may be the important factor [Rosensen RS et al. *Circulation* 2013]. In the arterial wall, lipid-laden macrophages drive the formation of atherosclerotic plaques, while HDL can promote the efflux and subsequent washing away of cholesterol [Rader DJ, Puré E. *Cell Metabol* 2005].

The Canola Oil Multicentre Intervention Trial [COMIT; NCT01233778] was undertaken in part to assess the effects of various edible oils on cardiovascular health in subjects with risk factors for metabolic syndrome. Specifically, COMIT assessed the effects of the selected oils on the efflux of cholesterol and the relationship with visceral adiposity.

The 101 participants (49 men, 52 women) satisfied the following eligibility criteria: age, 20 to 65 years; waist circumference \geq 90 cm (men) and \geq 80 cm (women); and at least 1 of the established metabolic risk factors of metabolic syndrome: elevated blood glucose, HDL-C, triglycerides, or blood pressure \geq 130/85. Subjects were not taking cholesterol- or glucose-lowering medications. Blood pressure medications were permitted.

The participants consumed diets elevated in canola oil, high oleic canola, high oleic canola supplemented with docosahexaenoic acid (DHA), corn/safflower, and flax/ safflower (Table 1). The order of each 4-week diet was randomized. There was a 2- to 4-week washout period in between each diet. The efflux of cholesterol from THP-1 macrophages was measured by an in vitro fluorescence



Table 1. Nutrient Profile of the Test Diets, %

	Canola Oil	High Oleic Canola	High Oleic Canola + DHA	Corn/Safflower	Flax/Safflower
SFA	6.60	6.50	6.90	6.70	6.80
MUFA	17.60	19.30	17.80	9.50	9.60
Oleic	15.70	18	16.50	8.30	8.40
PUFA	9.10	6.90	8	16.30	16.30
Omega-3 ALA	2	<1	<1	<1	6
Omega-3 DHA	_	_	1.10	_	_
Omega-6 LA	6.50	5.60	5.20	15.40	9.70

Based on 3000 kcal/d; protein, 15.60%; carbohydrate, 50.70%; fat, 35.50%. ALA=α-linolenic acid; DHA=docosahexaenoic acid; LA=linoleic acid; MUFA=monounsaturated fatty acid; PUFA=polyunsaturated fatty acid; SFA=saturated fatty acid.

Table 2. Baseline Characteristics

	Males (n = 49)	Females (n = 52)	
Anthropometric assessments			
Age, years	43.6 ± 1.7	49.9 ± 1.6	
Weight, kg	96.3±1.8	77.1 ± 1.4	
Body mass index, kg/m ²	30.9 ± 0.6	29.2 ± 0.5	
Waist circumference, cm	107.6 ± 1.1	96.4±1.2	
Metabolic syndrome risk factors			
Glucose, mmol/L	5.3 ± 0.1	5.4 ± 0.2	
HDL-C, mmol/L	1.2 ± 0.04	1.4 ± 0.04	
Triglycerides, mmol/L	2.0±0.1	1.6±0.1	
DBP/SBP*, mm Hg	80/128	79/122	

Values are mean±standard error of the mean. HDL-C, high-density lipoprotein cholesterol; DBP/SBP*, diastolic blood pressure/systolic blood pressure. *On May 1, 2015, "DPB" was changed to "DBP."

assay following the addition of serum obtained from the subjects during the study.

Baseline characteristics of the subjects are summarized in Table 2.

Ms. Liu then reported the results from the trial. Overall, the levels of HDL-C and apolipoprotein A1 were higher in the diet containing DHA and lower in the flax/ safflower diet (Table 3).

All diets significantly decreased total cholesterol, low-density lipoprotein cholesterol, apolipoprotein A1, and apolipoprotein B compared with baseline. All diets reduced triglycerides compared to baseline except the high-oleic canola diet. All diets significantly and similarly increased cholesterol efflux from macrophages compared to baseline. The levels of HDL-C were higher after consumption of the high oleic canola + DHA diet compared with the flax/safflower diet. Cholesterol efflux was negatively correlated with waist circumference at baseline (n=101; r =-0.25, p=.0115) and with abdominal fat mass (n=54; r =-0.33, p=.0173).

The results suggest that HDL-C plays a role in central obesity and atherosclerotic health, and they lend more evidence to the view that HDL-C concentration may not be reflective of HDL-C function.



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CLINICAL TRIAL HIGHLIGHTS

	Canola Oil	High Oleic Canola	High Oleic Canola + DHA	Corn/Safflower	Flax/Safflower
тс	4.83 ± 0.07	4.79 ± 0.07	4.89 ± 0.07	4.76 ± 0.07	4.71 ± 0.07
HDL-C	1.20 ± 0.02	1.18 ± 0.02	1.30 ± 0.02	1.20 ± 0.02	1.17 ± 0.02
LDL-C	2.91±0.07	2.87±0.07	3.03±0.07	2.85±0.07	2.84±0.07
TG	1.61 ± 0.07	1.65 ± 0.07	1.26 ± 0.07	1.58 ± 0.07	1.57 ± 0.07
TC/HDL ratio	4.29 ± 0.12	4.29 ± 0.12	4.01 ± 0.12	4.24 ± 0.12	4.28 ± 0.12
Apo A1	1.43 ± 0.02	1.44 ± 0.02	1.46 ± 0.02	1.42 ± 0.02	1.39 ± 0.02
Аро В	0.94 ± 0.02	0.94 ± 0.02	0.95 ± 0.02	0.92 ± 0.02	0.92 ± 0.02
Apo B / Apo A1 ratio	0.67 ± 0.02	0.67 ± 0.02	0.67 ± 0.02	0.67 ± 0.02	0.68 ± 0.02

Table 3. Levels of Lipids, Lipoproteins, and Apolipoproteins, mmol/L

Values expressed as mean±standard error of the mean. Apo=apolipoprotein; LDL-C=low-density lipoprotein-cholesterol; HDL-C=high-density lipoprotein cholesterol; TC=total cholesterol; TG=triglyceride.

On May 1, 2015, the LDL-C row was added to the table.

New Medical Device May Promote Long-Term Weight Loss

Written by Phil Vinall

Paul M. Stein, PhD, Onciomed, Irvine, California, USA, presented results showing substantial loss of weight in pigs after implantation of a novel restrictive bariatric medical device called the Onciomed Gastric Vest System (OGVS). In this animal study the minimally invasive implant device was safe, durable, and highly effective at enabling long-term weight loss with no apparent adverse effects.

In 2013, the American Medical Association declared obesity a disease [http://www.ama-assn.org/ama/pub/news/news/2013/2013-06-18-new-ama-policies-annual-meeting.page]. The incidence of obesity is increasing across the world. By 2020, obesity is expected to affect 672 million individuals, including 149 million in the United States. Obesity currently affects 1 in every 2 adults as well as 1 in 6 children younger than 13 years, and it is the number one cause of type 2 diabetes.

Dietary modifications, exercise, pharmaceuticals, medical devices, and gastric surgery are the most often used approaches to control weight. Patients are frequently not compliant with diet and exercise, and current pharmacological treatments have been associated with some adverse events that decrease adherence. Current devices for the treatment of obesity include balloons and balls that temporarily fill the stomach for 3 to 9 months, and liners or barriers that prevent nutrient absorption for ~ 9 months. The gastric band, which is delivered laparoscopically, is intended to be long-term treatment but has been found to occasionally slip off. Gastric surgery, although highly effective, is seen as the method of last resort. All gastric surgeries create either a banana shape or a small pouch out of the stomach that produces restrictions leading to less food intake and thus weight loss. Concerns with surgery include the long-term ramifications of losing large portions of the gastrointestinal tract (especially in the young), serious adverse events associated with bleeding and leaks from staple insertions, re-expansion of the stomach throughout time, and the potential for permanent malnutrition.

The OGVS was developed as a long-term medical implant that modifies the stomach into a banana shape, like in gastric surgery, but without removing portions of the stomach or allowing the stomach to re-expand throughout time. The device is designed to work by decreasing caloric intake, increasing satiety via neurohormonal responses, and improving gastric emptying. The device is implanted laparoscopically using a procedure that is easy to perform, quick (~40 to 60 minutes), and fully reversible.

Dr. Stein discussed results from a small study in pigs in which 3 received sham procedures and 7 received OGVS implants. The animals were followed for 9 months. Interest in food quickly waned within a week in the