

CLINICAL TRIAL HIGHLIGHTS

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

	Canola Oil	High Oleic Canola	High Oleic Canola + DHA	Corn/Safflower	Flax/Safflower
TC	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
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

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.

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 neuro-hormonal 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



implanted animals. After 3 months, body weight in the sham animals increased by 36%, whereas body weight in the implant animals decreased by 21%. There were no postsurgical complications, and all animals remained healthy throughout the study.

At the end of the study, animals receiving implants appeared lean. At necropsy, the internal and external appearance of the abdominal organs appeared normal in both sham and implanted animals. The OGVS was completely encapsulated in a thin sheath of white connective tissue. No tears were present, and no extension of the suture holes was noted. This device needs further study but may be a future option for the treatment of patients with obesity.

Benefits of Avocado Consumption in Overweight and Obese Subjects

Written by Brian Hoyle

Consumption of 1 avocado each day as part of a moderate-fat diet can lower low-density lipoprotein cholesterol (LDL-C) concentration and the number of low-density lipoprotein particles (LDL-P; determined by nuclear magnetic resonance) more so than a cholesterol-lowering low-fat diet or an avocado-free moderate-fat diet. The findings were presented by PhD candidate Li Wang, The Pennsylvania State University, University Park, Pennsylvania, USA.

Elevated LDL-C is a risk factor for cardiovascular disease and stroke. Avocados are a nutrient powerhouse that can lower LDL-C levels [Colquhoun DM et al. *Am J Clin Nutr* 1992; Lopez LR et al. *Arch Med Res* 1996; Pieterse Z et al. *Nutrition* 2005]. The number and size of LDL-P are also important in determining cardiovascular risk. Particles that are smaller and denser can more readily penetrate the arterial wall and promote plague formation.

The study assessed 4 diets (Table 1). The 45 subjects were randomly assigned to initially receive a lowfat, moderate-fat, or avocado diet for 5 weeks, with subsequent 5-week diet periods with the remaining 2 diets. Each diet period was separated by a washout interval (Figure 1).

Clinical visit involving blood draw and monitoring of vital signs was performed at randomization and after each 5-week diet period. The subjects were 21 to 70 years of age, were healthy, and had a body mass index of 25 to 35 kg/m² and LDL-C in the 25th to 90th percentile. Exclusion criteria were history of cardiovascular disease or diabetes mellitus, blood pressure 140/90 mm Hg, and use of cholesterollowering medications or supplements. Baseline characteristics are summarized in Table 2.

All 3 diets lowered total cholesterol and LDL-C compared to baseline. The reduction of LDL-C on the avocado diet was greater than the moderate- and low-fat diets. Triglycerides, very-low-density lipoprotein cholesterol, and intermediate-density lipoprotein

Table 1. Diets Used in the Study

Nutrienta	Average US Diet	Lower-Fat Diet	Avocado Diet	Moderate-Fat Diet
Percentage of total calories				
Total fat	34	24	34	34
SFA	12	7	7	7
MUFA	15	12	18	18
PUFA	7	5	9	9
Carbohydrate	51	~59	~48	~48
Protein	16	16–17	16–17	16–17
Fiber, g/day	15	25	35	25
Cholesterol, mg/day	336	< 200	< 200	< 200

MUFA=monounsaturated fatty acid: PUFA=polyunsaturated fatty acid: SFA=saturated fatty acid. ^aBased on a 2000-calorie diet.