SCIENCE

CRT-800.00

An Investigation of Plant-based, Mediterranean, Paleolithic, and Dash Diets

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BACKGROUND This study examines the impact of plant-based, Mediterranean, Paleolithic, and DASH diets on CVD risk factors.

METHODS Nondiabetic adults (ages 35-85)with one or more risk factors for CVD selected 1 of the 4 diet plans and then underwent a comprehensive nutrition education program prior to a 60 day diet intervention in which they kept a daily food log and met weekly with a multi-disciplinary study teams. Weight, blood pressure, fasting glucose, hemoglobin A1C, C-reactive protein, lipids, and lipoprotein particles were measured during an initial health screen, at 60 days, and 6 months post intervention.

RESULTS 279 subjects completed the 60-day dietary intervention (58 Vegan, 80 Mediterranean, 76 Paleo, 65 DASH), and 193 returned for 6-month follow-up, After 60 days on their respective diets, subjects lost an average of 9 lbs (4.7%, total 2,576 lbs) with improvements in BP across all groups. Subjects on the Vegan and Paleo diets lost the most weight (~6.5%) and showed the greatest improvement in lipid risk factors (11-14% decrease in LDL-P; 10-20% decrease in VLDL and TG).

CONCLUSION All four diets promoted weight loss and improved BP but had variable effects on lipid risk factors. Effects were greatest and sustained in those subjects that attended regular diet support group meetings.

Comparison Across Diets at 6 month follow up

Variable	WFPB (n=40)	Med (n=62)	DASH (n=39)	Paleo (n=52)
Women	82%	82%	90%	83%
Mean Age (years)	56.0	60.0	55.5	56.2
Weight at baseline (lbs)	194 ± 42	175 ± 42	201 ± 50	188 ± 42
Weight after 60 days	181 ± 42	171 ± 42	193 ± 48	176 ± 39
Weight after 6M	183 ± 45	172 ± 42	193 ± 50	176 ± 41
Mean Weight loss @6M, lbs (%)	11.1 (6.1%)	3.2 (1.8%)	8.3 (4.1%)	11.2 (6.0%)
% With Wt loss>5% @6M	60.0%	21.0%	26.9%	53.8%
BMI at baseline, mean BMI change @ 6M (kg/m²)	31.8 ± 5.7, -1.7	29.7 ± 6.2, -0.6	33.7 ± 7.0, -1.5	31.6 ± 6.9, -1.8
Change in SBP @ 6M	-13.9*	-6.1	-4.7	-12.0*
Change in DBP @ 6M	9.4*	-5.4*	3.3	-10.2*
Baseline glucose, change @ 6M (mg/dL)	93 ± 15, +7	92 ± 10, +3*	97 ± 20, +6	92 ± 9, +4*
Baseline HbA1c, change in HbA1C @ 6M (%)	5.4 ± 0.5, +0.2	5.2 ± 0.3, +0.1	5.4 ± 0.4, +0.1*	5.2 ± 0.3, +0.1
Baseline LP-IR, change in LP-IR @ 6M	45 ± 25, -3	43 ± 20, -5	54 ± 21, -9	39 ± 21, -8*
Baseline TG, change in TG @ 6M (mg/dL)	113 ± 63, +1	111 ± 94, -1	122 ± 74, -24	97± 59, 0
Baseline LDL-C, change in LDL-C @ 6M (mg/dL)	121 ± 34, -14	124 ± 43, -17*	131± 43, -14	123 ± 35, -10
Baseline LDL-P, change in LDL-P @ 6M (nmol/dL)	1261 ± 368, +82	1473 ± 436, -129	1524± 494, -33	1443 ± 405, -32
Baseline HDL-C, change in HDL-C @ 6M (umol/L)	70 ± 18, -13*	64 ± 14, -8*	62 ± 15, -6	65 ± 13, -5
Baseline HDL-P, change in HDL-C @ 6M (umol/L)	37.3 ± 5.5, +0.7	38.4 ± 7.2, +0.1	38.7± 6.6, +0.7	36.6 ± 6.0, +2.0

CRT-800.01

Glagovian Window of External Elastic Membrane Enlargement As Cornerstone Phenomenon of Artery Remodeling in Natural History of Atherosclerosis: Subanalysis of NANOM-FIM Trial

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BACKGROUND This subanalysis aims to explore Glagovian artery remodeling.

METHODS The artery remodeling in patients of NANOM-FIM trial (NCT01270139) was examined at the baseline and at 12-month follow-up (n=180) with 40 MHz intravascular ultrasound (IVUS).

RESULTS The polynomial regression analysis of a degree of six (R2=0.774) of IVUS confirmed existence of a window of the external elastic membrane (EEM) enlargement between 21% and 44% of per cent atheroma volume (PAV) in patients with a 30.7% decrease of PAV at 12-month follow-up. Patients with PAV below 21% have significant positive correlation between volumes of EEM, plaque and media which means naïve lumen. The trend between 21% and 34% is essentially the true Glagov phenomenon without lumen loss. The strength of that correlation was lost when PAV increased beyond 44% due to functional exhaustion of the compensatory EEM enlargement. The slowdown of the lumen narrowing in lesions with PAV above 63% documents advanced fibroatheromas with calcification. The serial assessments of IVUS showed a significant decrease at 12 months in the dense calcium area and fibro-fatty tissue in nano groups with an increase in necrotic core post-procedure and further reduction in size at 12 months ($p<0.05$).

CONCLUSION The PAV below 40-44% (a window of EEM enlargement of 21-44% PAV) after intervention guarantees restoration of the artery geometry with significant decline in clinical outcomes, which might become the optimal target for atheroregression strategies.

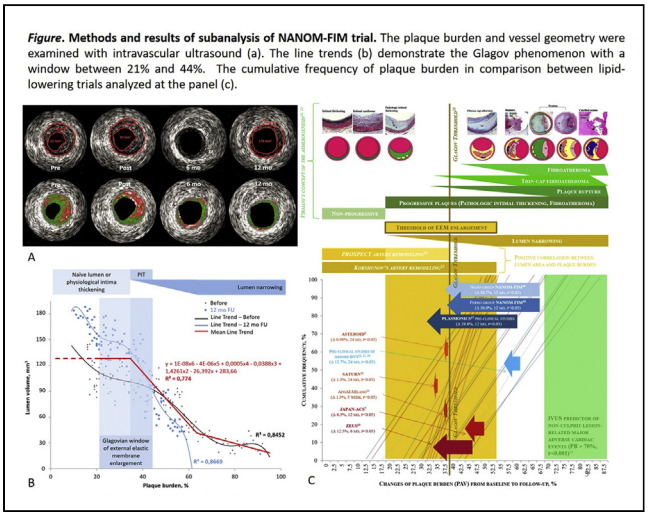

***Figure.* Methods and results of subanalysis of NANOM-FIM trial.** The plaque burden and vessel geometry were examined with intravascular ultrasound (a). The line trends (b) demonstrate the Glagov phenomenon with a window between 21% and 44%. The cumulative frequency of plaque burden in comparison between lipid-lowering trials analyzed at the panel (c).

CRT-800.02

Eligibility for PCSK9 Treatment in 734 Hypercholesterolemic Patients Referred to a Regional Cholesterol Treatment Center With Heterozygous Familial Hypercholesterolemia With LDL Cholesterol >100 Mg/dl and/or Atherosclerotic Cardiovascular Disease With LDL Cholesterol >70 Mg/dl Despite Maximal Tolerated Cholesterol Lowering Therapy

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BACKGROUND Lowering of LDL cholesterol (LDLC) has been revolutionized by the recent release of the PCSK9 inhibitors, Alirocumab (Praluent) and Evolocumab (Repatha). PCSK9 inhibitors have approved indications as an adjunct to diet and maximally tolerated statin therapy for patients with heterozygous familial hypercholesterolemia (HeFH), homozygous familial hypercholesterolemia (HoFH), or clinical atherosclerotic cardiovascular disease (CVD)where LDLC lowering is insufficient despite maximal tolerated cholesterol lowering therapy.

OBJECTIVE We have applied FDA approved and commercial insurance eligibility criteria for PCSK9 inhibitor use in 734 patients serially referred to our Cholesterol Diagnosis and Treatment center (within 3 years) and receiving ≥ 2 months maximally tolerated LDLC lowering diet-drug therapy with follow up LDLC ≥70 mg/dl. We obtained estimates of the nature of cohorts with high LDLC who meet FDA and commercial insurance eligibility for PCSK9 inhibitor treatment using LDLC goal-based guidelines.

METHODS We included 734 patients consecutively referred patients with LDLC ≥ 70 mg/dl after ≥2 months of maximally