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SHORT COMMUNICATION

Effects of a short-term intervention with a paleolithic diet in healthy volunteers

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Objectives: Prevention of cardiovascular diseases by paleolithic or hunterer-gatherer diets has been discussed during recent years.
Methods: Our aim was to assess the effect of a paleolithic diet in a pilot study on healthy volunteers during 3 weeks. The intention was to include 20 subjects, of whom 14 fulfilled the study. Complete dietary assessment was available for six subjects.
Results: Mean weight decreased by 2.3 kg ($P<0.001$), body mass index by 0.8 ($P<0.001$), waist circumference by 0.5 cm ($P=0.001$), systolic blood pressure by 3 mm Hg ($P=0.03$) and plasminogen activator inhibitor-1 by 72% ($P=0.020$). Regarding nutrient intake, intake of energy decreased by 36%, and other effects were also observed, both favourable (fat composition, antioxidants, potassium-sodium rate) and unfavourable (calcium).
Conclusion: This short-term intervention showed some favourable effects by the diet, but further studies, including control group, are needed.
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Introduction

It has been hypothesized that a change in the diet to one that more resembles that of hunter-gatherers would be beneficial to health, especially in preventing cardiovascular diseases (Eaton *et al*., 2002; O'Keefe and Cordain, 2004). Key features of the paleolithic diet are high intake of vegetables, fruits and meat; moderate intake of nuts, berries and honey; low intake of grains and no intake of milk or dairy products, legumes, salt, alcohol or refined carbohydrates (Cordain *et al*., 2000, 2002). The low salt intake could be expected to lower the risk of hypertension (Meneton *et al*., 2005). An earlier Australian study on 10 diabetic Aborigines revealed a marked improvement in carbohydrate and lipid metabolism by a more traditional life style (O'Dea, 1984). A recently published study on pigs showed an effect on insulin sensitivity, CRP and blood pressure (BP) (Jonsson *et al*., 2006). However, less is known of the effect on healthy free-living persons.

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Our aim was to assess the effect in healthy volunteers by a 3-week intervention with paleolithic diet on anthropometric and metabolic parameters. The diet concept was not an attempt to copy stone-age eating habits in a historically correct manner, but rather to eliminate some of the harmful aspects of modern affluent diets and extract some health benefits from readily available foods, using an evolutionary paradigm as guide.

Twenty healthy volunteers aged 20–40 years, 10 men and 10 women were recruited via the medical students' association at Karolinska Institutet in Stockholm, Sweden. Altogether 14 subjects fulfilled the study, 5 men and 9 women. One subject did not start, one missed the laboratory test, four broke the study, three because of illness and one could not fulfil the diet.

Exclusion criteria: Disease requiring hospital care or prescription drugs (exception: allergy – antihistamines), pregnancy, full-time breastfeeding, body mass index (BMI) above 30, eating disorder, special other diet. All subjects registered their entire food intake in a diary and later fed into a computer program (Dietist). Participants were recommended to weigh all ingredients, but were also supplied with a list of approximate weights of ingredients. Owing to a computer error, food registration data were available for eight subjects

regarding normal diet (two men, six women), and seven regarding paleolithic diet (one man, six women); complete data were available for six subjects (one man, five women).

The subjects were tested on three occasions, before run-in, after run-in (7 days) and after intervention period (21 days). Weight, height, waist circumference and BP were measured in a standardized way by the same person; BP was measured in the horizontal position after 5 min rest. Fasting blood samples were drawn (after 12 h fasting): haemoglobin, high-sensitive C-reactive protein (CRP), fasting blood glucose, insulin, lipids, fibrinogen, plasminogen activator inhibitor-1 (PAI-1) and homocystein. Glucose tolerance was calculated using the homeostatic model assessment 2 (HOMA2) model, based on fasting blood glucose and insulin (Wallace *et al*., 2004). The HOMA model has been shown a good correlation to euglycaemic clamp, otherwise the 'golden standard' in assessments of insulin resistance (Wallace and Matthews, 2002).

The diet concept used in the study was presented at a seminar before starting their intervention period, at the end of the run-in, together with a compendium.

Allowed food ad libitum: All fresh or frozen fruits, berries and vegetables except legumes, canned tomatoes without additives except for citric acid, fresh or frozen unsalted fish and seafood, fresh or frozen unsalted lean meats and minced meat, unsalted nuts (except peanuts), fresh squeezed lemon or lime juice (as dressing), flaxseed or rapeseed oil (as dressing), coffee and tea (without sugar, honey, milk or cream), all salt-free spices.

Allowed food in restricted quantity: Dried fruit (ad lib 2 days/week), salted seafood (one meal/week), fat meat (one meal/week), potatoes (two medium sized/day), honey (used in marinade once/week), cured meats (as entrée once/week), mineral water (only when drinkable tap water was not available).

Prohibited food: All milk and dairy products, all grain products (including maize and rice), all legumes (including peanuts), charcuterie products (for example, sausages, pâtés and so on), canned food (except tomatoes, see above) and all forms of candy, ice cream, sorbet, soft drinks, juices, syrups, liquor, sugar and salt.

Statistical calculations were performed by Stata version 9.0. Comparisons were performed by Student's paired *t*-test and Wilcoxon's paired test.

The study was approved by the Human Ethics Committee at Huddinge University Hospital (Dnr 593-03).

Anthropometric and laboratory data are shown in Table 1 ($n = 14$). Weight and BMI decreased in all participants, and also mean waist circumference, systolic BP and PAI-1. Two subjects showed elevated CRP, probably virus infection related.

Results from food registration are shown in Table 2 ($n = 6$). Energy intake (−36%) as intake of fat (−23%), especially saturated fat (−52%), and carbohydrates (−53%) decreased significantly, while intake of cholesterol increased (+68%). Besides, intake of vitamin B6 (+76%), C (+200%) and E (+69%) increased significantly, as did intake of potassium

Table 1 Mean values (s.d.) in 14 subjects in a short-term intervention with paleolithic diet

	Time 1	*Time 2*	*Time 3*	*Difference between time 2 and time 3*		
				Paired t*-test*		*Paired Wilcoxon*
				Difference (95% CI)	P-*value*	P-*value*
Weight (kg)	65.2	65.2	62.9	−2.3 (−2.7; −1.8)	0.0000	0.0010
BMI	22.2	22.2	21.4	−0.8 (−0.9; −0.6)	0.0000	0.0010
Waist (cm)	74.3	74.1	72.6	−1.5 (−2.3; −0.7)	0.0010	0.0016
Systolic BP (mm Hg)	110.1	106.8	103.8	−3.0 (−5.7; −0.3)	0.0300	0.0380
Diastolic BP (mm Hg)	65.0	63.4	61.0	−2.4 (−4.9; 0.1)	(0.0614)	(0.0955)
Heart rate (beats/min)	57.1	56.2	59.5	3.3 (−2.5; 9.1)	NS	NS
Hb (g/l)	126.9	127.6	126.4	−1.1 (−4.7; 2.4)	NS	NS
CRP (g/l)	0.7	0.8	2.4	1.6 (−1.2; 4.8)	NS	NS
Glucose (mmol/l)	4.6	4.5	4.6	0.1 (−0.2; 0.3)	NS	NS
Insulin (pmol/l)	30.6	27.7	24.6	−3.1 (−11.8; 5.5)	NS	NS
HOMA2%S	213	222	266	45 (−21; 110)	NS	NS
HOMA2 IR	0.56	0.51	0.46	−0.05 (−0.22; 0.12)	NS	NS
Cholesterol (mmol/l)	4.3	4.1	4.0	−0.2 (−0.4; 0.1)	NS	NS
Triglycerides (mmol/l)	0.8	0.7	0.7	−0.1 (−0.2; 0.0)	NS	NS
HDL-cholesterol (mmol/l)	1.4	1.4	1.3	−0.1 (−0.2; 0.0)	(0.0635)	(0.0684)
LDL-cholesterol (mmol/l)	2.5	2.4	2.3	−0.1 (−0.3; 0.2)	NS	NS
Fibrinogen (g/l)	2.3	2.2	2.3	0.1 (−0.2; 0.5)	NS	NS
PAI-1 (kIE/l)	5.0	6.7	2.8	−3.9 (−7.1; −0.7)	0.0197	0.0258
Homocystein (μmol/l)	13.1	12.2	11.8	−0.4 (−2.7; 1.9)	NS	NS

Abbreviations: BP, blood pressure; BMI, body mass index; CI, confidence interval; Hb, haemoglobin; HDL, high-density lipoprotein; HOMA, homeostatic model assessment; LDL, low-density lipoprotein; PAI-1, plasminogen activator inhibitor-1.
Time 1 is basement, time 2 after run-in period with normal diet and time 3 after 3 weeks with paleolithic diet. Differences between time 2 and time 3 are shown, also with *P*-values (when below 0.10) and 95% confidence interval (95% CI) for paired *t*-test, and *P*-values for Wilcoxon's paired sign-rank test.

Table 2 Mean daily intake of nutrients (s.d.) among participants in the study with complete food data intake, during the period with normal diet and that with paleolithic diet differences (95% confidence interval (CI)) with paired *t*-test and Wilcoxon's paired sign-rank test, with *P*-values

	RI	*Participants* (n = *6)*		*Difference*		*Paired Wilcoxon*
				Paired t-*test*		P-*value*
		Normal diet	*Paleolithic diet*	*(95% CI)*	P-*value*	
Energy (kcal)	M = 2800, F = 2200	2478 (269)	1584 (208)	−894 (−1133; −656)	<0.001	0.0277
Protein (g)	M = 107, F = 86	83.8 (14.8)	95.3 (28.5)	+11.5 (−18.0; +41.1)	NS	NS
E%	M and F = 10–15	13.5 (1.3)	23.9 (5.4)	+10.4 (+5.3; +15.6)	0.0035	0.0277
Carbohydrates (g)	M = 369, F = 293	335.3 (35.0)	158.3 (27.7)	−177.0 (−217.8; −136.2)	<0.001	0.0277
E%	M = 55–65 and F = 55–60	54.3 (3.7)	40.0 (4.9)	−14.3 (−22.4; −6.2)	0.0063	0.0277
Fat (g)	M = 87, F = 69	81.8 (13.1)	62.6 (8.5)	−19.2 (−28.1; −10.3)	0.0026	0.0277
E%	M and F⩽30	29.6 (2.2)	35.8 (4.1)	+6.1 (+2.9; +9.4)	0.0048	0.0277
Saturated fat (g)		31.3 (8.7)	15.0 (3.4)	−16.2 (−25.2; −7.2)	0.0056	0.0277
E%	M and F<10	11.4 (3.2)	5.5 (1.4)	−5.9 (−9.2; −2.6)	0.0058	0.0277
Monounsaturated fat (g)		26.4 (7.7)	28.9 (5.1)	+2.5 (−1.0; +6.0)	NS	NS
E%	M and F = 10–15	9.5 (2.3)	10.5 (1.5)	+1.0 (−0.3; +2.3)	NS	NS
Polyunsaturated fat (g)		13.0 (6.2)	13.4 (3.6)	+0.4 (−3.6; +4.4)	NS	NS
E%	M and F = 5–10	4.6 (1.8)	4.8 (1.1)	+0.2 (−1.1; +1.6)	NS	NS
Fibres (g)	M and F = 25–35	31.3	32.0	+0.7 (−3.6; +5.0)	NS	NS
Vitamin B6 (mg)	M = 1.5, F = 1.2	2.5 (0.8)	4.4 (0.9)	+1.9 (+0.9; +2.9)	0.0050	0.0277
Vitamin B12 (μg)	M and F = 2.0	5.4 (2.3)	16.3 (22.7)	+10.9 (−14.0; +35.8)	NS	NS
Vitamin C (mg)	M and F = 60	118 (52)	354 (61)	+236 (+136; +336)	<0.001	0.0277
Vitamin D (μg)	M and F = 5	7.6 (5.3)	8.5 (2.7)	0.9 (−5.6; +7.4)	NS	NS
Vitamin E (mg)	M = 10, F = 8	10.4 (4.8)	17.5 (3.7)	+7.2 (+3.8; +10.6)	0.0028	0.0277
Iron (mg)	M = 10, F = 15	15.1 (5.3)	14.3 (3.2)	−0.8 (−7.2; +5.7)	NS	NS
Calcium (mg)	M and F = 800	851 (160)	395 (81)	−455 (−623; −287)	<0.001	0.0277
Phosphorus (mg)	M and F = 600	1587 (404)	1300 (253)	−287 (−710; +136)	NS	NS
Magnesium (mg)	M = 350, F = 280	434 (150)	424 (51)	−10 (−143; +124)	NS	NS
Sodium (mg)	M and F = 2000	3115 (521)	1192 (181)	−1923 (−2470; −1376)	<0.001	0.0277
Potassium (mg)	M = 3500, F = 3100	3602 (577)	5228 (745)	+1626 (+902; +2349)	0.0022	0.0277
Potassium/sodium ratio	—	1.18 (0.23)	4.43 (0.67)	+3.26 (+2.53; +3.98)	<0.001	0.0277
Cholesterol (g)	—	0.25 (0.13)	0.42 (0.08)	+0.17 (+0.04; +0.30)	0.0197	0.0277

RI (Enghardt Barbieri and Lindvall, 2005) is recommended intake (M = males, F = females).

(+45%), while intake of calcium (−53%) and sodium (−62%) decreased.

Thus, we found a decrease in mean weight, BMI, waist circumference, systolic BP and PAI-1. The dietary pattern showed several favourable features, that is, a more favourable fat composition, higher intake of some antioxidants, vitamin C and E, and increased potassium/sodium ratio, which is favourable as prevention of hypertension (Ayoob *et al*., 2002; Suter *et al*., 2002). A negative effect is the decreased intake of calcium, which could be a risk factor for osteoporosis later on in life (Villareal *et al*., 2006). Despite a higher total energy rate of fat and of cholesterol, the blood lipids value did not increase.

This study has some limitations. Only 14 out of intended 20 subjects fulfilled the dietary intervention, which caused the study to become underpowered. Besides, dietary data could only be retained from six subjects, and hence correlation analyses were not adequate to perform. However, the low number of subjects with dietary data was sufficient to show a difference in the intakes of different nutrients.

It is concluded that a short-term intervention with a paleolithic diet in healthy volunteers showed some favourable effects on cardiovascular risk factors. Further studies are needed, with a larger sample size and a control group included.

Abbreviations

PAI-1, plasminogen activator inhibitor-1; HOMA, Homeostatic model assessment; CRP, C-reactive protein.

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