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Original Article

Assessing compliance with Paleolithic diet by calculating Paleolithic Diet Fraction as the fraction of intake from Paleolithic food groups

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SUMMARY

Background: Dietary compliance assessments are absent in clinical studies on Paleolithic diet. We therefore developed a 'Paleolithic Diet Fraction' (PDF), calculated as the fraction of intake from Paleolithic food groups, to assess compliance with Paleolithic diet in a previously reported study.
Methods: 29 male patients with ischemic heart disease, impaired glucose tolerance and waist circumference > 94 cm, were randomized to a Paleolithic or Mediterranean-like diet for 12 weeks. Mean daily PDFs were calculated for dietary energy and weight for all participants using four-day weighed food records, and linear regression analysis was performed between PDF and primary outcome measures plus leptin for both diet groups combined.
Results: PDFs were just above 80% for the Paleolithic diet group and around 40% for the Mediterranean-like diet group. We found associations between PDF and outcome measures of similar strength as previously reported for group differences, and an association with weight, for which no group difference was previously found.
Conclusions: Calculation of PDF demonstrated a mean compliance of just above 80% in the Paleolithic diet group and association

Abbreviations: AUC, Area under the curve; OGTT, Oral glucose tolerance test.

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studies indicated a clinical relevance for PDF. Trial registration: ClinicalTrials.gov NCT00419497 retrospectively registered.

1. Introduction

Modern chronic diseases such as coronary heart disease, hypertension and diabetes are absent among recent hunter-gatherer populations [1]. Based on this epidemiological observation, it has been proposed that the diet of recent hunter-gatherer populations may be ideal for preventing modern chronic diseases [1]. The suggested theoretical underpinning of the proposition is that modern chronic diseases arise due to insufficient genetic adaptation to a recently (in evolutionary terms) introduced agricultural diet [1]. The diets of recent hunter-gatherer populations are thought to most closely resemble that of preagricultural human populations during the late Paleolithic [1]. Therefore, when the general dietary pattern of recent hunter-gatherer populations was described, it was called a Late Paleolithic diet [1]. The composition of a Late Paleolithic diet, or just "Paleolithic diet" as it is now usually referred to, was specified on a basis of included and excluded food groups, and included fruits and vegetables, roots and tubers, beans, lean meats, eggs and nuts; it excluded grains, dairy products, refined fats and sugar [1]. Legumes such as beans were later also excluded from a Paleolithic diet because of their late (mostly post-agricultural) incorporation into the human diet and associated risks, which include high levels of phytic acid, lectins, protease inhibitors, alkylresorcinols and phytoestrogens [2–4]. The Paleolithic diet has now been tested in interventional studies with encouraging results on risk factors for modern chronic diseases. However, one important methodological feature usually missing from intervention studies on Paleolithic diet is a measure of compliance.

Compliance in a clinical intervention study is defined as the degree of adherence to a prescribed intervention by study participants [5]. In a dietary clinical intervention study, such as the interventional studies on the Paleolithic diet, a measure of compliance would therefore be a measure of how completely the study participants followed the recommended diet. Since the Paleolithic diet composition primarily is based on included and excluded food groups, we propose that a relevant measure of compliance would be the fraction between the summed intake of all food groups included in the Paleolithic diet and the summed intake of all food groups. In this paper, we have calculated such a fraction, hereafter referred to as the Paleolithic Diet Fraction (PDF), to assess compliance in a randomized controlled trial (RCT), which compared a Paleolithic diet with Mediterranean-like dietary advice according to standard clinical practice, in patients with ischemic heart disease and impaired glucose tolerance or type 2 diabetes [6]. We have previously reported from this study greater improvements in the group randomized to the Paleolithic diet in glucose tolerance, reduced waist circumference, greater satiety per calorie and a trend towards greater relative reduction of the satiety hormone leptin [6,7].

2. Methods and materials

The previously reported study performed in 2005 was a 12-week RCT in 29 male patients with ischemic heart-disease, waist circumference >94 cm and known type 2 diabetes or, at a screening oral glucose tolerance test (OGTT) with 75 g glucose, a fasting capillary blood glucose $\geq$6.1 mmol/l or a 2 h capillary blood glucose $\geq$7.8 mmol/l [6,7]. Participants were randomized to one of two diets: a Mediterranean-like diet (n = 15) based on whole-grain cereals, low-fat dairy products, potatoes, legumes, vegetables, fruit, fatty fish, and refined fats rich in monounsaturated fatty acids and alpha-linolenic acid, or a Paleolithic diet (n = 14) based on lean meat, fish, fruit, vegetables, root vegetables, eggs and nuts (for more details on study population and intervention see [6,7] and Table 1).

Table 1
Daily food consumption.

Paleolithic diet group N = 13		Mediterranean-like diet group N = 14	
Weight, total (kg)	**1.5 ± 0.6**	**Weight, total (kg)**	**1.7 ± 0.3**
Weight from Paleolithic food groups (kg)*	1.3 ± 0.7	Weight from Paleolithic food groups (kg)*	0.8 ± 0.3
Weight from non-Paleolithic food groups (kg)**	0.2 ± 0.2	Weight from non-Paleolithic food groups (kg)**	0.9 ± 0.3
Paleolithic Diet Fraction for weight (%)**	86 ± 17	Paleolithic Diet Fraction for weight (%)**	46 ± 14
Energy, total (MJ)*	**5.8 ± 2.6**	**Energy, total (MJ)***	**7.7 ± 1.2**
Energy from Paleolithic food groups (MJ)*	5.0 ± 3.0	Energy from Paleolithic food groups (MJ)*	3.0 ± 1.1
Energy from non-Paleolithic food groups (MJ)**	0.8 ± 1.0	Energy from non-Paleolithic food groups (MJ)**	4.7 ± 1.0
Paleolithic Diet Fraction for energy (%)**	83 ± 20	Paleolithic Diet Fraction for energy (%)**	39 ± 12
Paleolithic food groups		*Paleolithic food groups*	
Fruits (g)*	515 ± 350	Fruits (g)*	259 ± 174
Vegetables (g)	311 ± 202	Vegetables (g)	198 ± 78
Meat (g)*	198 ± 108	Potatoes (g)	87 ± 80
Fish (g)	114 ± 93	Fish (g)	73 ± 48
Potatoes, ≤ 1 medium-sized/day (g)	64 ± 49	Meat (g)*	72 ± 52
Wine, ≤1 glass/day (g)	62 ± 67	Wine, ≤1 glass/day (g)	37 ± 51
Eggs, ≤ 2/day (g)	33 ± 38	Eggs (g)	22 ± 24
Nuts, in limited amounts (g)*	10 ± 12	Oil (g)	2 ± 3
Oil, rape seed or olive oil, ≤ 1 tbsp/day (g)	0 ± 0	Nuts (g)*	1 ± 3
Non-Paleolithic food groups		*Non-Paleolithic food groups*	
Meat products (g)	67 ± 100	Milk/milk products (g)**	311 ± 169
Milk/milk products (g)**	39 ± 102	Cereals without rice (g)**	262 ± 87
Juice (g)	37 ± 72	Juice (g)	85 ± 139
Cereals without rice (g)**	21 ± 50	Meat products (g)	82 ± 66
Beer (g)	11 ± 27	Sweet beverages (g)	45 ± 103
Beans (g)	9 ± 22	Sauce (g)*	34 ± 67
Bakery (g)	3 ± 8	Beer (g)	29 ± 55
Sauce (g)*	1 ± 5	Beans (g)	21 ± 34
Jam (g)	1 ± 3	Rice (g)*	20 ± 27
Sweet beverages (g)	1 ± 2	Bakery (g)	9 ± 23
Rice (g)*	0 ± 0	Jam (g)	6 ± 9
Spirits (g)	0 ± 0	Spirits (g)	3 ± 7

Average food eaten per day and participant on the Paleolithic or Mediterranean-like diet excluding non-energy containing beverage such as table water, coffee and tea. Values are means ± SD. Estimated from four day weighed food records. Food groups sorted in descending order by consumption and as Paleolithic or non-Paleolithic based on diet recommendations for the Paleolithic diet in this study, which recommended increased intake (or allowed limited intake as specified) of Paleolithic food groups and to avoid all intake from non-Paleolithic food groups. *$P < 0.05$ and **$P < 0.0001$ for difference between groups in a Mann–Whitney U test.

Approval for the study was obtained from the Medical Ethics Committee at Lund University, and all individuals gave written informed consent to participate in the study.

Food intake during the study was assessed from each participant's reports of four day weighed food records. Dietary nutrient content from reported food intake was calculated from the contemporary Food Database of the Swedish National Food Agency ([6] and Table 1). Groupings of food intake were retained from previous publications of results from this study ([6,7] and Table 1) and are for all intents and purposes consistent with the food group classification of the Food Database of the Swedish National Food Agency [8], which classifies food groups according to the European Food Information Resource (EuroFIR) [9]. Food groups were sorted into Paleolithic and non-Paleolithic based on the Paleolithic diet recommendation of the study ([6,7] and Table 1). The PDF was calculated for all participants as the mean daily fraction between the summed intake of all food belonging to the Paleolithic food groups and the summed intake of all food ([6,7] and Table 1), both by energy and weight. For unknown reasons, one participant from each group did not perform a food record and could not be included in the analyses.

2.1. Statistical analysis

The Mann–Whitney U test was used to analyze differences between groups and simple linear regression analyses were used to analyze associations between the PDF for energy or weight and

the primary outcome measures plus leptin. For unknown reasons, two participants from the group randomized to a Mediterranean-like diet did not perform waist circumference measurements and could not be included in the association analyses. $P < 0.05$ was chosen as statistically significant and has not been corrected for multiple testing since conducted analyses are exploratory [10]. However, due to multiple testing and the post hoc nature of these calculations cautious interpretation of the results is called for.

3. Results

The PDF and total absolute intakes of Paleolithic and non-Paleolithic food groups differed between groups with a PDF for weight of 86% and a PDF for energy of 83% in the group randomized to a Paleolithic diet and a PDF for weight of 46% and a PDF for energy of 39% in the group randomized to a Mediterranean-like diet (Table 1). There were weak associations between the PDF and the following changes in outcome measures during study; area unde the curve (AUC) for glucose during the OGTT, weight, waist circumference and leptin (Table 2), and those associations were almost identical with those between PDF and relative changes in the same outcome measures during study (unpublished results).

4. Discussion

Mean compliance in the group randomized to a Paleolithic diet was just above 80%, as indicated by the PDF. Although less than a desirable compliance of 100%, it hopefully indicates the truthfulness in dietary reporting of the participants. To our knowledge, the only previous measures of compliance from interventional studies on the Paleolithic diet are by Frassetto et al., who used 24-h urinary sodium and potassium excretions as markers for dietary compliance [11,12], and by Bisht and Lee et al., who in their studies on the impact of a multimodal intervention on Multiple Sclerosis reported the percentage of days and servings fully adherent to a modified Paleolithic diet [13,14]. The requirement used by Bisht and Lee for full adherence was a self-reported food record showing consumption of any recommended foods and no consumption of excluded foods [13,14]. This way of measuring compliance is an all or nothing approach to Paleolithic diet studies. This may be relevant for studies on autoimmune diseases such as Multiple Sclerosis, where a day or serving with even a miniscule intake of excluded foods could have detrimental effects [15]. However, for modern chronic diseases such as coronary heart disease, hypertension and diabetes, whose prevention and treatment are dependent on the number and severity of relevant risk factors, a relative dosage measure of the Paleolithic diet such as the PDF could be more relevant as a measure of compliance.

Table 2
Association between Paleolithic Diet Fraction (PDF) and change in outcome measures during study.

Dependent	Predictor	N	A	B	CI for B	aR^2	P[a]
AUC glucose during OGTT (mmol/L*min)	PDF for energy	27	−23	−2.7	−5.1 to −0.2	0.14	0.03
	PDF for weight	27	−2.4	−2.8	−5.5 to −0.1	0.12	0.04
AUC insulin during OGTT (mmol/L*min)	PDF for energy	27	−1.4	−0.3	−0.6 to 0.1	0.05	0.1
	PDF for weight	27	−2.1	−0.2	−0.7 to −0.7	0.02	0.2
Weight (kg)	PDF for energy	27	−1.94	−0.04	−0.08 to 0.00	0.13	0.04
	PDF for weight	27	−1.2	−0.1	−0.1 to 0.0	0.16	0.02
Waist circumference (cm)[b]	PDF for energy	25	−0.7	−0.1	−0.1 to 0.0	0.23	0.01
	PDF for weight	25	0.3	−0.1	−0.1 to 0.0	0.26	0.01
Leptin (%)	PDF for energy	27	4.8	−0.5	−0.8 to −0.2	0.28	0.003
	PDF for weight	27	9.1	−0.5	−0.9 to −0.2	0.26	0.004

Results from simple linear regression analysis between predictor PDF (%) for energy or weight and dependent change in outcome measure during study. The model formula for the resultant relationships is: dependent = A + B * predictor. N; number of participants included for the analysis. aR^2; adjusted R squared. CI; Confidence Interval. AUC; Area under the curve. OGTT; Oral glucose tolerance test.

[a] P for association significance.

[b] For unknown reasons, two participants from the group randomized to a Mediterranean-like diet did not perform waist circumference measurements and could not be included in the analyses.

Compliance cannot be estimated in observational studies, since, by study definition, there is no intervention to comply with. However, similarity between the observed diet and the Paleolithic diet can be estimated, as Whalen et al. and later Haridass et al. did by calculating for each individual a semi-quantitative relative score for a Paleolithic diet pattern from food frequency questionnaires [16–19]. Interestingly, Whalen et al. also based their Paleolithic diet pattern on included and excluded food groups similarly to our PDF. Furthermore, they demonstrated its clinical relevance in association studies where greater similarity with Paleolithic diet was inversely associated with mortality and biomarkers of inflammation and oxidative balance, as well as with a lower risk of incident, sporadic colorectal adenomas [16–18].

To implement such association studies in both study arms and thereby assess its clinical relevance, the PDF was also calculated for the group randomized to a Mediterranean-like diet, revealing a mean PDF of around 40%. Albeit not a measure of compliance in the group recommended a Mediterranean-like diet, the clear difference in PDF between the two groups is a useful illustration of how well the two groups were separated by the design and execution of the study, as well as an indication of the clear difference in dietary composition between the two diets. Association studies in both groups combined were then performed with linear regression analyses between the PDF and changes during study in weight, waist circumference and AUC for glucose and insulin, which were the predefined primary outcome measures reported in 2007 by Lindeberg et al. in the first publication of results from this study. Similar association studies using linear regression analyses were also performed between the PDF and changes during study in the secondary outcome measure leptin, which was central in the second publication of results from this study in 2010 by Jönsson et al. The strength of the resulting associations between the PDF and our primary outcome measures plus leptin were similar to previously reported results for group differences in glucose tolerance, waist circumference and leptin, but was also found for weight, for which no group difference was previously found.

4.1. Strengths

The Food Database of the Swedish National Food Agency used for calculating the PDF and the food composition in the previously reported study is an updated, researcher independent and locally well-established food database with high credibility. Since the reliability of the PDF is dependent on the consistency and overall quality of food group classification, it was considered a strength basing food group affiliation for reported food items on the classification of the Food Database of the Swedish National Food Agency.

4.2. Weaknesses

Lack of an externally validated and fixed list or index when deciding which food items and food groups are Paleolithic is a weakness. Calculating the PDF for other studies can be a problem if their Paleolithic diet recommendations differ. Although the division of food groups as Paleolithic or non-Paleolithic in this study appears to be the same as those used for most studies on the Paleolithic diet, some studies have also excluded potatoes, which were included as Paleolithic in restricted amounts in this study. Another weakness of the PDF as calculated in this study is that it is based on only four-day weighed food records, which are prone to reporter bias. Other weaknesses of this study are its small study sample, short duration and the post hoc nature of the present analyses.

4.3. Future studies

Using the PDF as a possible way of assessing compliance in future Paleolithic diet studies is important since compliance can have a significant impact on the results of any study and is a methodological element utilized to assess the causal implication of the intervention's impact [5]. Furthermore, this measurement of compliance can allow for comparison and partial control of differences in results between studies due to intervention adherence, either through post hoc stratification or

statistical adjustment [5]. We propose using the food group divisions from this study when calculating the PDF for comparison between studies, and a study specific modified PDF, if needed, to account for differences in Paleolithic diet recommendations when assessing compliance.

5. Conclusions

Our PDF indicated a mean compliance of just above 80% in the Paleolithic diet group and association studies indicated a clinical relevance of the PDF. Further studies are warranted.

Declarations

Approval for the study was obtained from the Medical Ethics Committee at Lund University (LU 665-02) and all individuals gave written informed consent to participate in the study.

Conflict of interest

None.

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Authors contribution

All authors made substantial contributions to all of the following: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content, (3) final approval of the version to be submitted.

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