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Commentaries and Rebuttals to "Unrestricted Paleolithic Diet is Associated with Unfavorable Changes to Blood Lipids in Healthy Subjects" in *International Journal of Exercise Science* 2014

Paper in preparation

Introduction

Several clinicians and researchers were recently (2014 Aug-Sept) involved in a casual conversation via email regarding the merit and shortcomings of the recent publication "Smith et al, Unrestricted Paleolithic Diet is Associated with Unfavorable Changes to Blood Lipids in Healthy Subjects. *International Journal of Exercise Science* 2014;7(2);128-139 <http://digitalcommons.wku.edu/ijes/vol7/iss2/4/>." Despite our busy schedules and the relative unimportance of this publication in a non-indexed journal, a few of us nonetheless decided to contribute a few critiques of the article so that the discussion and scientific record could be better balanced. What follows are commentaries provided by several of us in favor and/or against this publication.

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Alex Vasquez DC ND DO FACN (Bogota, Colombia): My initial reaction and critique of the article is objection to the apparent bias that the authors embed in the title of their article. Their title "Unrestricted Paleolithic Diet is Associated with Unfavorable Changes to Blood Lipids in Healthy Subjects" rapidly conveys the inaccuracy of their perspective and failure to include better balance, objectivity, and fairness in reporting their findings, which notably included the positive findings "improvements in body composition and cardiorespiratory fitness." Why did the authors omit these positive findings from their headline-grabbing title? This impressive omission suggests if not indicates an inherent goal or bias among the authors in slandering "the Paleo diet." Secondly, a very reasonable argument could be made that "improvements in body composition and cardiorespiratory fitness" (physiologic and phenotypic markers) are more important than "unfavorable changes to blood lipids" (laboratory markers) which reflect what many consider to be an outdated paradigm of cardiovascular risk. Thirdly, I find their advocacy and description of an "ad libitum" and "unrestricted Paleo diet" to be absurd, since any reasonable diet should include prudence and, generally, some restriction on intake; furthermore, the accurate historical context of the Paleo diet is generally noted to include periodic food scarcity (not "unrestricted" access to an ad libitum diet) as well as abundant physical exercise, the latter of which was excluded from this study, thereby rendering it an incomplete model and representation of the Paleo diet and lifestyle in its contextualized totality.

Maelán Fontes Villalba, MS (Lanzarote, Canary Islands, Spain): When I read that manuscript I found that they didn't have the food records from all the participants (I think this was written in the online version prior to the paper publication) nor did they document what the participants ate. I can't think of a dietary intervention without knowing what did the participants eat! Also, they have no control group, a very important limitation.

Oscar Picazo, MS (Madrid, Spain): First and foremost, and as Dr. Vasquez has pointed out, the title is misleading, as the intervention included not only an uncontrolled version of a paleo diet, but a Crossfit exercise program for 10 weeks. This omission is crucial, and should have been included in the title. The authors start with a critic on the inconsistency of dietary interventions with the paleo diet along several studies, and point that an ad libitum paleo diet, without macronutrient defined limits, could result in a diet high in fats, and not in accordance with AHA dietary guidelines. The intervention section describes the prescribed paleo diet, where no specific macronutrient recommendation was made. Although it is true that a paleo diet may have a flexible macronutrient profile, it is also true that, at least from our research group, we do not advocate a low carb approach, as has been popularized in the blogosphere. However, even if the subjects adopted a high protein – high fat diet, the literature has described positive effects in the short term (<6 months) in cardiometabolic profile, due to reduction of refined sugars and grains in low carb interventions, when compared to the standard American diet. At any rate, making guesses about the baseline and intervention nutrition profile, is all the reader can do, as no dietary analysis is offered. There is no description of the macro-, micro- or type of foods consumed before and during the intervention. The authors clearly state that they intended to collect the food records for all the participants, but only could collect 8 out of 44. This is a sign of poor adherence by the participants, or poor control by the researchers. With regards to lipid levels, there are statistically significant (but clinically insignificant) increases in TC, LDL (calculated by Friedewald), and non-HDL cholesterol, a non-significant increase in TG, and a non-significant decrease in HDL. I wish the authors detailed the TG levels, in order to calculate the TG/HDL ratio, marker not used by the authors, but that correlates very well with body composition, insulin resistance, and lipoprotein particle profiles. It seems from the graph, that this ratio is around 1.25 for both before and after the intervention, at any rate, a good marker as most studies seem to indicate a TG/HDL lower than between 2 or 3 as an indicator of good metabolic health. As the authors correctly point out, exercise generally has positive effects on HDL and TG, modest on LDL and TC, but can also result in worsening of lipids level if the intensity of the program is not adequate. The modest changes in blood lipid levels, could be due to diet change, or due to exercise, we simply do not know. Not knowing the baseline diet, is a big concern here, as a diet rich in W6 PUFA could result in lowered baseline lipid levels. Concerning body composition, a significant decrease in body fat was registered, and additionally, a significant increase in VO_{2max}. There are unfortunately no

indications of lean mass after the study, abdominal perimeter, or even weight or BMI, given in table 1 (before) but not after the intervention, a very important omission. The authors state that this intervention reflects more precisely the normal dietary habits of Paleo dieters. I wonder how can they state that, when there is no indication whatsoever of what were they eating; maybe some had an almost vegetarian diet, while others would feast on eggs and bacon. I agree that an intervention diet has to be well designed, not only in the context of studies, but of course for the general population. It is true that there are concepts I would point as not fully correct in the so-called Paleosphere, as the general low-carb approach, and the popularity of some processed foods (the infamous “bacon” and “paleomuffins”). If what the authors mean is that a wrongly implemented paleo diet could be deleterious, they are right. But they have not proved at all that a well-set up intervention, as the ones used in Lindeberg, Frassetto or Jönsson studies, would result in worse health markers. To conclude, I think a more representative title would have been “An unknown dietary intervention and a cross-fit program are associated with modest changes in blood lipids and improved body composition and VO_{2max} ”. The idea of testing the paleo diet on healthy subjects seems interesting, but it is a pity the resources were not used to at least split the sample in a randomized controlled trial, testing only diet without exercise. It seems that what the authors wanted to debunk, is the "Crossfit+Paleo" movement. If that was their intention, I do now think the result has been successful, due to the study limitations.

Vasco Névoa, Eng (Lisbon, Portugal): Adding to the aforementioned items, I see that the authors relied on flawed laboratory methodology with regards to the LDL-c assessment. The Friedewald equation is only valid within a “normal” range of serum Triglycerides level between 100 and 400 mg/dL; above 400 it underestimates LDL-c, and below 100 it grossly overestimates it. The intervention group of this study shows an average TG clearly below the 100 threshold (typical of low-carb dieters), and therefore the LDL-c should have been directly measured and not indirectly estimated. Even assuming that the better laboratory tests were not available to this study (for, say, budgetary reasons), there are new versions of the Friedewald formula that have been corrected for this problem and are capable of good adjustment to the real curve, as was published for example in “AHMAD I, Seyed-Ali, et al. The impact of low serum triglyceride on LDL-cholesterol estimation. Arch Iran Med, 2008, 11.3: 318-21.” At this point it may become tempting to argue that the error should be linear and proportional and would cancel out between the baseline and final values, not affecting the outcome; however the whole issue with the inadequacy of the Friedewald formula at certain ranges is born from the fact that the physiological relationship between TC, TG, HDL and LDL is not linear and therefore that assumption cannot be made without proof. I estimate that the overestimation of this group's baseline LDL is around 8% which is a large value in this context, but I have no way of calculating the deviation at the end of the intervention because the full data is apparently not published. This defect in the application of the Friedewald formula is a recurring theme in low-carb diet studies where the authors' bias towards criticism prevents them from correctly analysing and employing the technology at hand, perpetuating fear, doubt, and uncertainty instead of helping clarify the issue. As a final note, please understand that Low-Carb is not equal to Paleo, and there is evidence that our ancestors generally ingested a vast variety and amount of fruits, vegetables and honey, aside from animal products. I emphasize this point because, although the dietary details of the study were not disclosed, the TG levels below 100 mg/dL clearly point to a low-carbing population being used in it which, as bears repeating, is not the same as a Paleolithic nutrition. Paleo can be implemented at any level/combination of macronutrients, and typically will vary depending on availability, individual preference, and local culture.