Reviewer's report

Title: Effects of the prudent diet versus low fat diet in the management of patients with chronic hepatitis C

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Reviewer: Prachi Sharma

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Minor Essential Revisions:

OVERALL COMMENT: A very interesting study, but please correct the spelling errors and the use of incorrect tense. The incorrect tense is confusing, because the reader is unable to follow, if you are making a general statement or mentioning what was specifically done in your study. E.g. Page 5-Moderate exercise is (WAS?) recommended for all persons with hepatitis C who are not experiencing decompensated cirrhosis or 6 other metabolic complications.

My suggestions/edits are in parenthesis next to the word which should be changed-

1. Page 1: Background Chronic hepatitis C (CHC) can be considered a metabolic liver disease which implies: insulin resistance (IR), increased prevalence of impaired glucose tolerance or type 2 diabetes mellitus (T2DM), changes in lipid metabolism, (AND A) high prevalence of steatosis.

2. Page 1 We want (WANTED) to measure the impact of dietary changes in reduction of insulin resistance, obesity but also in steatosis and fibrosis.

3. Page 1: All subjects signed an (A) written informed consent

4. Page 2: At 12 months, FPG, FPI and HOMA-IR had significant improvements in both groups. With both diet aspartataminotransferase (ASPARTATE AMINOTRANSFERASE), alaninaminotransferese (ALANINE AMINOTRANSFERASE), gamma-glutamil transpeptidase (GAMMA-GLUTAMYL TRANSPEPTIDASE) decreased with significant differences; also there were significant improvements in AST/ALT ratio, AST/Platelets ratio and Forns index.

5. Page 2: Patients with hepatitis C following a lifestyle intervention for 1-year had significant improvements in (BEING) overweight or obesity, fasting glucose, fasting insulin, HOMA-IR, lipidic, (AND) hepatic profile with both diets.

6. Page 2: Chronic hepatitis C (CHC) can be considered a metabolic liver disease which implies: insulin resistance (IR), increased prevalence of impaired glucose tolerance
or type 2 diabetes mellitus (T2DM), changes in lipid metabolism, (AND A) high prevalence of steatosis.

7. Page 2: TRIAL DESIGN This multicenter, randomized controlled trial was conducted during (FROM) September 2007 - December 2010.

8. Page 3: The inclusion criteria were: age over 35 years, diagnosis of chronic hepatitis C (CHC infection was defined by the presence of anti-HVC (HCV) for at least 6 months and a positive (POSITIVE) HCV-viremia).

9. Page 3: Patients with other etiology of chronic liver diseases, hepatitis B, autoimmune liver disease, hemochromatosis, HIV infection, patients with history of hepatotoxic or steatosis-inducing drug use, treatment with interferon in the last 12 months, patients having an alcohol consumption (CONSUMPTION OF) more than 20 g/day for women and 30 g/day for men, history of pancreatitis were excluded from the study.

10. Page 3: Eligibility was established during a screening visits (VISIT) that included a medical history and physical examination.

11. Page 3: The primary endpoint is (WAS) to measure the impact of dietary changes in reducing (REDUCTION) of the insulin resistance and hepatic steatosis and fibrosis by nutritional intervention.

12. Page 3: Participants whose average blood pressure levels were greater or equal to 140/90 mmHg or with (IS THERE A WORD MISSING HERE?) antihypertensive medication were classified as hypertensive subjects.

13. Page 4: Insulin, peptide C and cytokines (CYTOKINES) as adiponectin, leptin, resistin, interleukin-6 (IL-6), tumor necrosis factor (TNF-alpha) were measured at baseline and 12 months.

14. Page 4: The oral glucose tolerance test (OGTT) was performed in patient (PATIENTS) with HbA1c higher than 5.5%.

15. Page 4: Diabetes diagnostic was made according (IN ACCORDANCE) with criteria ADA 2003.

16. Page 4: For metabolic syndrome (MetS) we use (USED THE) definition according to IDF criteria.

17. Page 5: All patients completed at (A) baseline, 6 and 12 month a 4-day food record, including two working days and the weekend, at baseline (before the randomization visit) and before every visit.

18. Page 5: Dietitian doctors instructed participants to follow a diet with approximately 50-60% of daily caloric intake from carbohydrate [15], 25-35% of total calories from fat (less than 7% of total calories from saturated fat, less than
1% trans fatty acids, 10% monounsaturated fatty acids, 5-10% polyunsaturated fatty acids (PUFAs) and less than 300 mg cholesterol per day), proteins 15% of total calories (1.0 to 1.2 g/kg/day) [16], and <5% of caloric intake from simple sugars.

19. Page 6: The two test (TESTS) of normality used were Kolmogorov-Smirnov with a Lilliefors significance corection and Shapiro-Wilk statistic.

20. Page 6: At baseline, in both groups, there were not (NO) statistically significant differences between patients who completed the study and those who dropped out.

21. Page 7: The degree of PA increased in the first 6 months in both groups (WAS ?) statistically significant; even if in the next 6 months PA was reduced, the difference between baseline and 12-months remained statistically significant in both groups (for PD the difference was 56.5 min/week [95% CI, 46.4,66.6] and 39 min/week [95% CI 28.7, 49.3] for LFD.

22. Page 8: The were no significant differences in the 12-month percentages change in FPG, FPI, peptid (PEPTIDE) C, homeostasis model assessment for insulin resistance and, homeostasis model assessment for #-cell function, between groups.

23. Page 8: With both diet aspartataminotransferase (ASPARTATE AMINOTRANSFERASE), alaninaminotransferese (ALANINE AMINOTRANSFERASE), gamma-glutamil transpeptidase (GAMMA-GLUTAMYL TRANSEPTIDASE) decreased with significant differences; also AST/ALT ratio, AST/Platelets ratio and Forns index had significant improvements.

24. Page 8: If patients are (WERE) stratified according to grade of weight loss (weight gain - Group A, 1-5% weight loss - Group B, 5-10% weight loss - group C and weight loss above 10% - Group D) there is (WAS) observed an improvement in liver function parameters.

25. Page 10: The effects of lifestyle changes on hepatic inflamation (INFLAMMATION) and fibrosis have been more variable [29,30], one single study reported its improvement.

26. Page 10: Limitations of the study are: for patients with CHC, we used the noninvasive methods to estimate steatosis and fibrosis and this (THESE) indices are not so high (HIGHLY) sensitive and specify (SPECIFIC).

27. Page 10: The objectives of diet therapy in chronic hepatitis C are: providing a balanced nutritional intake, reducing the effects of the associated metabolic disorders and minimize (MINIMIZING) the progression to cirrhosis or hepatocellular carcinoma.

Quality of written English: Needs some language corrections before being published
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests