

Review Form 1.6

Journal Name:	Journal of Advances in Medicine and Medical Research
Manuscript Number:	Ms_JAMMR_94272
Title of the Manuscript:	Lipid Abnormalities among Libyan HIV-Infected Patients Receiving Antiretroviral (ARV) Drugs and ARV Naïve Patients
Type of the Article	Original Research Article

General guideline for Peer Review process:

This journal's peer review policy states that **NO** manuscript should be rejected only on the basis of '**lack of Novelty**', provided the manuscript is scientifically robust and technically sound. To know the complete guideline for Peer Review process, reviewers are requested to visit this link:

(<https://www.journaljammr.com/index.php/JAMMR/editorial-policy>)

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PART 1: Review Comments

	Reviewer's comment	Author's comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)															
<p>Compulsory REVISION comments</p>	<p>1. The authors should clearly state the specific objectives of their research. For lack of specific objectives, the authors seem to have lost track during their analysis and reporting. While they called their research a case control study with HIV positivity indicating cases and HIV negativity indicating controls, most of their results are a comparison between ART and non-treated HIV patients. If this study had HIV-negative participants as the controls, then results should majorly provide a comparison with this control group. The other differences should be reported as secondary objectives including the difference between ART-treated and non-treated HIV patients. Therefore, data should be re-analyzed to focus on well stated specific objectives</p> <p>2. The method section need a lot of improvement especially by providing the following</p> <ul style="list-style-type: none"> a) Justification of the sample size of participants. The authors appear to be reporting clinically significant difference while their sample size is actually insufficient. It is scientifically misleading to our readers to present differences in lipid profiles between ART-treated and non-treated HIV patients when there were actually only 20 non-treated patients versus 101 HIV/ART participants. There must be an epidemiological evidence (formula for instance, or other researches), to show that the numbers are sufficient for the outcomes reported. b) Kindly revise your reporting on numbers in order to remove inconsistencies. Your abstract reports 101 ART treated HIV patients, 20 non-treated HIV patients and 70 HIV negative participants. The Numbers of non-treated HIV patients change to 28 in the method section and then to 21 in the results section. These change raise a question on the authenticity of your report. If not done already, please provide your original data set to the journal. Also provide searchable authors and their affiliations. c) Did you collect your samples from patients originally designed for this study, or did you use samples that were either stored or samples from another ongoing study. You need to come out clear on this because there are gaps in your report that raise suscription. You called this a case control study to show high reliability of your data, however, you start your methods section by showing it is a laboratory based study, you also seem to have lost control in balancing the numbers of controls Vs cases. This would n't have happened in a true case control study since you concurrently look for the control of each recruited case. If it is a true case control as you report, kindly provide all characteristics of your cases and your controls; provide details of where your controls were recruited so we may see if the environment rhymes with cases; and provide then a reason why you have many more cases than the controls. However, if you used samples of an already ongoing or completed study, it would be understandable if you have differences in numbers of comparable groups, and also if you failed to control for some confounding factors. d) As already advised above, reanalyse your data to reflect comparisons between your HIV positive and negative patients following specific objectives that you will state. e) Include a statement on ethical clearances and provide the IRB/ EC protocol numbers for your study. Of course you need to attach a scanned copy of the EC approval letter for your study. This shall also increase on the authenticity of your work. <p>3. I advise that you include a table of baseline characteristics somewhere at the begging of your results section. This table should show different baseline characteristics with their respective results of the key outcome parameters. This will help to show if some of your findings were contributed by confounders. See example below, but add other relevant baseline characteristic especially those that may confound your results.</p> <table border="1" data-bbox="649 1690 1647 1892"> <thead> <tr> <th>Baseline characteristic</th> <th>Total Cholesterol</th> <th>LDL</th> </tr> </thead> <tbody> <tr> <td>F(n= or--- %)</td> <td></td> <td></td> </tr> <tr> <td>M (n= Or ---%)</td> <td></td> <td></td> </tr> <tr> <td>Age bands</td> <td></td> <td></td> </tr> <tr> <td>CD4 categories 0-199</td> <td></td> <td></td> </tr> </tbody> </table>	Baseline characteristic	Total Cholesterol	LDL	F(n= or--- %)			M (n= Or ---%)			Age bands			CD4 categories 0-199			
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M (n= Or ---%)																	
Age bands																	
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	<p>200-349 350-500 >500</p> <p>HIV Status HIV/ART HIV positive, no ART HIV Negative</p>				
	<p>4. Include a report on comparison of lipid levels for different ART categories you have in your study (NRTI+ NNRTI; NRTI + PI; NSTI + NRTI etcetera)</p>				
Minor REVISION comments	<p>Your statement that 'due to shortage of research data related to HIV infection.....' is scientifically incorrect. Please state the exact gap which your research intended to address. Moreover you go ahead in your discussion, to include substantial information on HIV/ART and Lipidemias. It would also help to include in your literature section, some of the mechanisms by which HIV and some ARVs cause hypercholesterolemia. When you show exactly data that is available, it becomes easy for our readers to see the gap you covered in your research.</p> <p>Revise your result section to remove unnecessary figures, including those showing differences in demographics. Figures are often reserved for data directly reporting results for your specific objectives: results related to cholesterol, per se. Information for figures 1-4 should be included in a general table for demographics and you may perhaps include just one overall figure at this stage.</p> <p>Could you revise your figure 6 and focus on your X-axis on different Cholesterol states rather than on HIV status. Your report focuses on lipids as an outcomes and not on HIV status. Therefore the X-axis should have graphs for TC, LDL, HDL while the different HIV states (HIV/ART, HIV Only and HIV negative) are indicated by differences . Do the same for figure 8 because again your outcome is ALT, AST etcetera.</p> <p>In your results for CD4/ CD8, please include results for HIV negative participants. That will bring out a complete report, in case the parameter is a confounder.</p> <p>When it comes to clinical relevance of your report, table 4 shows that only 9 out of your total study population (121 HIV positive + 70 HIV negative), had high cholesterol results. The limitation of the number of participants enrolled should come out very clearly in order for you to have a well balanced report.</p> <p>You indicated some of your results as change in ALT or AST, not being significant. How many times did you measure your parameters? You can't talk of change for a parameter measured once. Please revise your report.</p>				
Optional/General comments	<p>The authors seem to have done their work or written their report in a hurry and therefore made many errors which even lead to questioning the authenticity of their work. I recommend that if the research was actually done, authors should take time to analyse their data and write a scientific report, giving attention to every detail.</p>				

PART 2:

	Reviewer's comment	Author's comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
Are there ethical issues in this manuscript?	<p><i>(If yes, Kindly please write down the ethical issues here in details)</i></p> <p>Yes, there is no mention as to whether the research work had ethical oversight</p>	

Reviewer Details:

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