Author's response to reviews

Title: Correlates of quality of life of overweight and obese patients: a pharmacy-based cross-sectional survey

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Version: 2 Date: 26 March 2009

Author's response to reviews: see over
March 26, 2009

Re: Revision of the manuscript: Correlates of quality of life of overweight and obese patients: a pharmacy-based cross-sectional survey

Dear Sir, Dear Madam

Please, find below the replies to the comments. We did our best to address the different points raised by the reviewers.

We have also added in the revised manuscript the detailed contributions of the different co-authors. Please note that the last two authors may not meet the criteria to qualify as authors. Please feel free to move them to the acknowledgements section and consequently remove them from the list of authors.

Should you have any additional questions, please do not hesitate to contact us

Best regards

Dr Laurent Laforest on behalf of Dr Van Ganse
Reviewer's report:

Major Compulsory Revision

1. Background.
   This section start with a sentence which refer to chronic diseases in general. Successively, the Authors state about the prevalence of obesity. This is somewhat confusing. I think it should be rephrased. We have extensively amended the Background section into 3 main paragraphs: 1- obesity, 2- QOL issues, 3- The reasons for investigating QOL correlates in obese patients (please, see the revised version).

   Only patients with BMI>=28 were enrolled. However, as the Authors state, the aim of the study was to investigate QOL in overweight patients. It seems to me that overweight patients are a minority in this study given the BMI cut off used to define the inclusion criteria. We acknowledge that the threshold chosen in the study (≥ 28 kg/m²) does not comprise all overweight patients. Our more restrictive definition of overweight ruled out borderline and less severe overweight patients.

   The Authors should explain why the OSQOL was chosen for this study. This may result in its internal consistency, and should present briefly previous experiences with this instrument. The choice of OSQOL was motivated by the wish to have a specific questionnaire rather than a generic instrument. Unfortunately, we are not aware of any prior experience with the OSQOL questionnaire.

   The identification of comorbid diagnoses is a very relevant problem. The Authors acknowledged partially this problem in the limitations section when they state that diagnoses for whom no drug was prescribed were not identifiable. However, can the Authors explain how was determined the co-morbidity diagnosis from drugs used for more than one possible disease (e.g. ace-inhibitors: heart failure? hypertension? Diabetic nephropathy?)? Indeed, this is a pivotal point. We acknowledge that our definitions of co-morbid conditions were somewhat approximate. Indeed, some drugs were not specific to a studied disease, like ACE-inhibitors. In such cases, as only regular patients were included in the study, pharmacists were oriented by patients’ medical history. We added the following sentence in the Method section (§ Data collected, last sentence): “In case of isolated unspecific therapy (C03, C07, C08), pharmacists were oriented by patient’s medical history.”

   Our aim was to assess a burden of associated co-morbid condition, as approached by prescribed therapy for the most common chronic diseases, rather than to define precise diagnoses. This is the reason why we used the number of associated diagnoses, rather than detailed specific conditions.

3. Results.

   BMI varied from 28 to 51 (median=32). Overweight patients (25<BMI<30) are only a minority. The Authors should consider to change the referral to overweight throughout the manuscript. We thank the reviewer for noticing this point. We have changed “overweight” into “overweight or obese” patients throughout the manuscript.

   Univariate analysis: Please describe univariate analysis before introducing results from multivariable models (as on page 8). A specific paragraph is devoted to univariate results page 9 (§3-Univariate correlates).

4. Discussion.
The Authors should consider to discuss the impact of obesity on QOL in the light of recent findings suggesting that psychological well being is one of the most important correlates of QOL, both in the physical and in the mental domains (Corica et al, Int J Obes 2008). We warmly thank the reviewer for drawing our attention to this point. This useful reference illustrates some of our results, such as the impact of BMI on the physical component of QOL. The reference has been cited in the Discussion with comparison with our findings.

The underlined statement has been added to the following sentence: “Domains referring to relations with others and psychological distress were only partially studied as only a single item was dedicated to these dimensions in the OSQOL. Given the role of psychological welfare in QOL (Corica), further studies with more elaborated instruments are needed to investigate these topics more accurately.”
Reviewer's report
Title: Correlates of quality of life of overweight patients: a pharmacy-based cross-sectional survey

Version: 1 Date: 13 January 2009
Reviewer: Katherine Applegate

Reviewer’s report:
• Major Compulsory Revisions : NONE
• Minor Essential Revisions

1) Abstract: In the US, the grouping of “self-employed” workers and “top executives” would not occur because these labels are generally associated with different socio-economic categories. Please adjust or clarify the term “self-employed” for this context. Indeed, in our manuscript “Self-employed” corresponded to “professional persons”. We have changed this term throughout the manuscript.

2) Background section: The first sentence of the second paragraph is difficult to read, please rephrase. Also, same paragraph, change to “…between obesity and cardiovascular disease…” not diseases, no subject verb agreement. We acknowledge that these sentences were not clear. We have extensively rephrased this paragraph as follows: “The consequences of obesity and more generally excess weight on mortality and morbidity (ref), notably cardiovascular diseases, are well established (ref). Likewise, the consequences on osteo-articular and endocrinal morbidity should not be overlooked (ref).”

3) Background section, paragraph 3: The authors state that understanding factors that influence QoL could impact interventions for obesity. This is not necessarily accurate, but at least, should be more thoroughly explained. We have elaborated this paragraph as follows: “Increasing our existing awareness of factors influencing QOL in this population may be helpful in terms of public health. Indeed the potential identification of sub-groups of patients with poor QOL may be a preliminary step before implementing preventive action for improved management of overweight and obesity.”

4) Background section, paragraph 3: Please expand on the age related reference as it relates to this study. This sentence was awkward as we had no reason to specifically focus on age. As a consequence, for higher clarity we have removed it. Moreover, the corresponding paragraph has been extensively amended. Nonetheless, this sentence could be re-inserted in the manuscript if the reviewer or the editor judge it relevant.

5) Background section: Specific hypotheses to be tested by this study would be helpful prior to beginning the Methods section. This would also better define the questions to be tested in the study. We thank the reviewer for drawing our attention to this point. We aimed at knowing to which extent OSQOL scores varied according to patients’ and disease characteristics. Our aims are stated at the end of the Background section.

6) Background section: Please discuss in this section the rationale or benefit of using pharmacies as the study site, as the recruitment location represents a unique and relevant aspect of this study. Indeed, this pivotal issue was missing. We thank the reviewer for drawing our attention to this point. This is an interesting alternative to recruitment by physicians. However, we judged this point important enough to insert the additional paragraph in the Discussion section rather than in the Background.

We have added the following to the last paragraph:
“An originality of the PRICARDO pharmacy-based study was its design. Studies on chronic diseases have been successfully conducted in pharmacies. Pharmacists with whom patients often have a relationship of confidence are ideally positioned to conduct such studies, notably in case of regular or chronic therapy. Our results proved the feasibility of such a study in the context of overweight and obesity. On the other hand, only a specific sub-population of patients is more likely to be easily captured in pharmacies: those needing a regular treatment.”
7) Methods: How representative is this sample for France compared to the general population? This is an interesting question, although very difficult to answer. Our sample cannot claim to be representative in any way of the overall population of obese patients, which was acknowledged in the Discussion section. In turn, our study population may reflect that of obese patients receiving a regular therapy.

What percentage of the population is on a prescription medication? In our study all recruited patients presented at least one prescribed drug.

8) Methods: Please expand on why this assessment of QoL was used compared to other measures. Indeed, there were numerous alternative outcomes to investigate. In the present manuscript, we wanted to focus on quality of life with its different dimensions. Other outcomes may be studied in further manuscripts.

9) Methods: Data collection section, paragraph four has a spelling error (pour). Thank you for noticing this typo that we have corrected.

10) Methods: Do many people in this population participate with more than one pharmacy? This could affect the assigned medical diagnoses tally. In theory, this may have been possible, the more so as self-questionnaires were anonymous. However, this was very unlikely. In our sample, no patient exhibited concomitantly the same age, gender, BMI, waist circumference and socio-professional status.

11) Results: How may have the limited question items on dimensions 3 and 4 affected the results. Ideally, the assessment of these domains would have been more comprehensive. We acknowledge that this is a limitation of our approach. This noteworthy point has been mentioned in the Discussion section (limitations): “Domains referring to relations with others and psychological distress were only partially studied as only a single item was dedicated to these dimensions in the OSQOL. Given the prominent role of psychological welfare in QOL [ref], further studies, with more elaborated instruments are needed to investigate these topics more accurately.”

12) Discussion: Please clarify how the age difference (i.e. reference to younger patients) may have impacted relationship domain. Data seems limited to conclude it is related to physical appearance.

Our conclusions have been downplayed as follows in the Discussion:

“Our data suggest that younger patients are more affected in their relationships by their excess weight. A potential explanation might be physical appearance, as it may play a more important role in the social life of younger patients. Indeed, excess weight may be a barrier to developing social activities in younger patients whereas older overweight patients may have become accustomed to their appearance meaning that the impact on their social life is much less important. However, these hypotheses require confirmation and, more generally, a better understanding of the effects of age on relationship domain is desirable.”

13) Discussion: What criteria were the pharmacists using to determine if a patient should be approached to participate in the study? Only physical appearance was used by the pharmacist to select patients. Then, selected patients were proposed to participate and they completed a self-questionnaire. BMI was computed based on height and weight reported in the questionnaires. Patients were included if BMI ≥ 28 kg/m².

14) Discussion: Is there any data available on these patients’ mental health status or usage of psychotropic medication? This would have been of major interest to investigate a potential correlation between mental health and the amount of dispensed psychotropic medication. Unfortunately, these data were not available in our study.

• Discretionary Revisions NONE
Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Acceptable
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.
Reviewer's report:
The article examines the effects of number of patient characteristics on different dimensions of QoL in sample of obese patients presenting themselves in a local pharmacy. The authors conclude that obesity has a negative impact on all four dimensions of QoL and that future research on QoL in obese patients should take patient characteristics such as age, gender, SES, dietary habits and physical activity into account. Although these conclusions are useful for future research, a number of issues arise when reading the manuscript. These issues have to be addressed to make the manuscript suitable for publication.

Major compulsory revisions:
I will list them following the structure of the manuscript.

1. The background section needs to be extended. For example, the first paragraph contains two sentences, which are not well connected. Indeed, the first sentence was not fully appropriate in this context. We have extensively reorganised the Background section into 3 main paragraphs: 1- obesity, 2- QOL issues, 3- The reasons to investigate QOL correlates in obese patients.

More background information would be useful. The background section has been extensively reorganized. More details have been provided on the results of previous studies dealing with QOL of obese patients.

“Obesity may also have detrimental consequences on patients’ health-related QOL, particularly their physical functioning [ref]. In contrast, the impact of obesity on mental components of QOL yielded more controversial conclusions [ref]. Increasing our existing awareness of factors influencing QOL in this population may be helpful in terms of public health. Indeed the potential identification of sub-groups of patients with poor QOL may be a preliminary step before implementing preventive action for improved management of overweight.”

2. The second paragraph explains that “excess weight is detrimental to patients’ QoL”. One might wonder why the current study is needed when we already know that excess weight negatively influences different aspects of QoL? The background paragraph has been extensively amended. The interest of our study was to determine the correlates that influenced QOL in a population of obese patients in pharmacies. This point has been stated in the second part of the Introduction.

3. The methods section: the way the respondents are selected is problematic. First of all, the convenience sample is not representative for the obese population, which hampers generalizations and policy recommendations. The authors state this in the limitations section. Indeed, our sample was not representative of the overall population of obese patients, which has been acknowledged in the Discussion section. In contrast, our study may be more representative of the sub-population of middle-aged/elderly overweight patients requiring frequent or chronic drug therapy. We believe that this sub-population may not be uncommon and is of interest in terms of public health as chronic diseases are common in obese patients (Torres et al 2006), notably at a given age.

In addition, our conclusions are in line with those of other authors. Another additional interest of the study was to investigate the possibility of conducting in pharmacies studies focused on obese/ overweight patients under treatment.


But the second problem is much more serious. The authors select their respondents in local pharmacies, which results in the fact that only obese patients who visit their pharmacy can be included
in the study (one can argue that all people visit the pharmacy at least from time to time, but this still means that patients who visit the pharmacy more often have a greater chance to be included into the sample). This type of sampling results in a ‘selection bias’: patients who regularly visit the pharmacy have some kind of medical problem and are therefore expected to have poorer QoL. We have acknowledged that we focused on a specific sub-population of overweight/obese patients visiting regularly pharmacies. Consequently, these patients may present a higher burden of co-morbid diagnoses than a more representative sample of obese patients. Nonetheless, we believe that such selection bias may not substantially affect our findings:

- Firstly, it must be kept in mind that the OSQOL score is specific to obesity.

- Although the burden of associated co-morbid diagnoses may contribute to impair the “physical” and the “vitality” dimensions of OSQOL, the impact on the two others (“relation with others”, “psychological state”) may be more questionable. Interestingly, our results are supportive of this assumption: the relationship between the number of associated co-morbid diagnoses and QOL scores reveals that physical and vitality scores are significantly affected only beyond two co-morbid diagnoses (Table 3). Furthermore, no significant effect was noted in multivariate analysis (Table 4). Also, the influence of associated co-morbid diagnoses was more limited on the other OSQOL scores. These findings suggest that this selection bias may not substantially affect our conclusions.

- Lastly, most of our findings are consistent with those of previous studies.

The authors select their respondents on the basis of a criterion that is heavily associated with the dependent variable (QoL). The sample will most probably underestimate the QoL of the obese population. Indeed, this risk cannot be formally discarded, as our study population was not representative of the general population of obese patients. Nevertheless, this potential underestimation of QOL did not prevent us from identifying QOL correlates in accordance with those of previous published studies.

This can also disturb the other associations (as for example poor obese people with a good QoL do not visit the pharmacy and rich obese people with good QoL do to buy expensive beauty products). This may not be the case in the French system. Virtually all French patients are covered by the National Health System for their prescribed medications, although a minority of homeless people and patients facing serious financial difficulties may refrain from buying their therapy.

Even though beauty products are commonly sold in French pharmacies, no luxury product can be found. More importantly, the activity of pharmacies remains mainly focused on dispensing medications. Lastly, virtually all prescribed drugs can be purchased only in community pharmacies. To conclude, even though under-representation of patients with low socio economic status and good QOL cannot be formally excluded its impact on our findings may be assumed to be limited.

4. Measuring patients’ relations with other people and their psychological state with only one question seems too narrow. It is very difficult to measure these complex interactions and emotions with only one item. The authors should explain the limited validity of these measurements. We agree with the reviewer. We have expanded on this point in the Discussion section (underlined part has been added):

“Domains referring to relations with others and psychological distress were only partially studied as only a single item was dedicated to these dimensions in the OSQOL. Given the role
of psychological welfare in QOL (Corica), further studies with more elaborated instruments are needed to investigate these topics more accurately.”

5. The conclusions do not seem very innovative. The findings that older people and people of lower socio-economic status have poorer QoL are general socio-medical phenomena that are not restricted to obese people. This is true. However, the originality of our work was to study a sub-population of obese patients attending pharmacies. Indeed, the correlates of QOL identified in this specific sub-population may not be systematically similar to those identified in the general population.

Minor essential revision:
1. Typo: second to last paragraph of the methods section: ‘pour’ should be ‘poor’ This point has been corrected. We thank the reviewer for drawing our attention to this point.

To conclude, the manuscript provides interesting information on the factors influencing different aspects of QoL in an obese sample of patients. However, the conclusions do not seem really innovative (as conclusions have already been reported in other studies) and there are serious problems with the sampling procedure (selection bias probably causing an underestimation of the QoL) which curtail the reliability of the conclusions. All our conclusions are in line with those of previous surveys, as underlined by the reviewer. Nonetheless, an originality of our survey was that it was conducted in pharmacies, which has been mentioned in the Discussion section. Furthermore, an additional analysis has been added to study the relationship between BMI and the OSQOL scores according to the other factors (Table 4, revised version). This provides an additional originality to our findings.

Language: OK, although I am not a native speaker.

Statistics: OK

Level of interest: An article of limited interest
Quality of written English: Acceptable
Statistical review: Yes, and I have assessed the statistics in my report.
Declaration of competing interests: I declare that I have no competing interests.
Reviewer's report:

This study reports data from a convenience sample – with an unreported and possibly unknown response rate - of pharmacy customers with a BMI >= 28 in the Rhone-Alpes Region (France). Reported data focus on obesity-specific quality of life. While being of potential interest to audiences with related research interests, to my assessment this manuscript is undecided as to what it wants (see my remark 1.). Also, the outcome instrument (OSQOL) is very imperfect in terms of psychosocial QOL (remark 2). Finally, the limitations associated with studying pharmacy customers should be discussed - not only the strengths of this design (remark 3). Also, there are a number of minor essential and discretionary revisions I suggest (remarks 4 + following).

Major Compulsory Revisions

1.

1.1- To me, this manuscript is undecided as to what it wants. Does it aim to identify correlates of OSQOL in a sample of adults with excess body weight, while adjusting for BMI? Or does it aim to explain existing differences in OSQOL across BMI-groups by sociodemographic/-economic factors, behavioural factors, and (co-)morbidities? If it is the former, then one comes to the description of the results the authors offer in the respective section of their abstract – and, to be honest, in my view these variations of OSQOL by age, SES, and gender do not sufficiently add new insights to our field of inquiry. However, I suppose that the authors’ “real” aim in fact is a different one - namely to explain existing OSQOL-differences across BMI-groups by third variables, i.e. sociodemographic, socioeconomic, and behavioral factors, and [co]-morbidities.

Our initial aim was to identify the correlates of OSQOL questionnaires, BMI and others. In our models, the severity of overweight was always taken into account in our multivariate analyses were systematically adjusted for BMI (Table 4).

However, these hypotheses really deserve investigations. We have expanded these points in the Result section (see paragraph below).

1.2-. For instance, regarding Table 2 the authors state that the “influence of excess weight on psychological and relational dimensions was also significant, with 22.3 % feeling ill-at-ease due to excess weight and 19.6 % feeling attacked when people talked about their weight” (p. 8). Clearly, this refers to OSQOL-differences by BMI (even though surprisingly, such differences are not even reported in the table), which should then be explained by other variables. We acknowledge that this sentence was awkward as this paragraph only aimed at describing the different OSQOL scores (effect of BMI is investigated in the next paragraph (Table 3). Consequently, we rephrased the sentence as follows (RESULT section, §2- QOL scores): “A noticeable proportion of patients reported that they felt ill-at-ease due to excess weight (22.3 %), or attacked when people talked about their weight (19.6 %).”

1.3- Also, in the Discussion the authors state that the result that physical OSQOL declined with BMI “can be partly explained by the osteo-articular and respiratory consequences of excess weight” (p. 10). This again points to the aim of explaining differences across BMI-groups, which however HAS not been done even though it COULD have been done with the present data. This interesting analysis was not included in our initial objectives. We fully agree that it would provide novelty and a substantial additional interest for our manuscript. We warmly thank the reviewer for this helpful suggestion. This analysis has been added in the manuscript (Table 3, see end of the present document).

- The following paragraph has been added in the Method section (results paragraph): “Complementary analyses were also conducted to assess to which extent the relationship between BMI and the different OSQOL scores varied according to other patients’ characteristics.”
The corresponding results are summarised in Table 3 (revised manuscript)

Comments have been added in the Result Section (§3- Univariate correlates):

“The relationship between BMI and the different OSQOL dimensions according to the other factors did not show significant changes (Table 3).”

and in Discussion (2\textsuperscript{nd} § Interpretation of results)

As one final example, later in the Discussion it’s said that “Regular exercising provides physical and psychological well-being to patients regardless of the severity of their excess weight ... This was confirmed by our results where patients’ efforts to increase physical activity significantly improved physical functioning” (p. 11-12). Well, no - the authors do not test (or at least not report any test on) if/how physical activity improves OSQOL in each BMI-group. We found that patients who reported previous efforts for substantial changes in their physical activities had significantly better scores for OSQOL physical dimension (table univariate results). Besides, multivariate Model 1 adjusted for BMI yielded similar conclusions (Table 5, revised version).

What the reviewer suggests (to which extent physical activity interferes with the OSQOL-BMI relationship) is interesting, but a distinct analysis from our initial goal. Given their originality and interest, these analyses have been added in the revised version (Table 4). Stratified analysis BMI x OSQOL according to physical activity does not noticeably alter our previous conclusions, notably percentages of patients presenting a low QOL across the different BMI categories (table below).
When the relationship between physical activity and QOL was studied separately in each BMI class, no noticeable change was observed. This was corroborated by the absence of significant interaction between the corresponding variables: please see paragraph (c) below.

Of note, the difference in p-values may only be attributed to the very unbalanced counts of patients who changed their habits and those who did not (n=79 vs. n=386)

All in all, in order to make sufficiently more of the data, it should be reanalysed as follows:

(a) Probably replacing Table 2 for reasons of space, it should be reported how the three BMI-groups (28-29.9, 30-34.9, ≥ 35) are composed of in terms of age, gender, occupational status, current smoking, alcohol consumption, number of associated co-morbid diagnoses, previous efforts to change diet and previous efforts to change physical activity - and if BMI is associated with these variables. Results in Table 2 corresponded to our initial objective. However, as mentioned above, we are most happy to follow the reviewer’s interesting suggestion as to complementary analyses (Table 4, revised manuscript):
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<th>BMI (kg/m²)</th>
<th>Age (years)</th>
<th>Gender</th>
<th>Socio-economic status</th>
<th>Current smoking</th>
<th>Alcohol</th>
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<td>n</td>
<td>% ≤ Q25% score (3)</td>
<td>p</td>
<td>% ≤ Q25% score (3)</td>
<td>% 'Fairly true' or 'absolutely true'</td>
<td>% 'Fairly true' or 'absolutely true'</td>
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<td>.224</td>
<td>9.7</td>
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<td>.1034</td>
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<td>30 – 34.9 kg/m²</td>
<td>156</td>
<td>21.2</td>
<td>.250</td>
<td>15.4</td>
<td>.02613</td>
<td>.1067</td>
</tr>
<tr>
<td>≥ 35 kg/m²</td>
<td>125</td>
<td>40.8</td>
<td>.336</td>
<td>29.6</td>
<td>.0115</td>
<td>.1067</td>
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<td>.0005</td>
<td>.1067</td>
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<tr>
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<td>.0613</td>
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<tr>
<td>30 – 34.9 kg/m²</td>
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<td>42.1</td>
<td>10.5</td>
<td>.0006</td>
<td>.1067</td>
</tr>
<tr>
<td>≥ 35 kg/m²</td>
<td>23</td>
<td>52.2</td>
<td>.522</td>
<td>43.5</td>
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<td></td>
<td>.0002</td>
<td>.2312</td>
</tr>
<tr>
<td>&lt; 29.9 kg/m²</td>
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<td>15.6</td>
<td>.208</td>
<td>18.2</td>
<td>.0006</td>
<td>.2312</td>
</tr>
</tbody>
</table>
(b) Logistic modelling should follow a hierarchical approach, i.e. in such a way that variables that can be hypothesised to be able to explain higher odds of poor QOL in severely and moderately obese compared to those in pre-obesity range (BMI= 28-29.9) are entered consecutively after the BMI-group-factor to see if the ORs of the obese groups are attenuated. If this is the case, and at the same time there is an association between BMI and the variable under scrutiny, there is evidence for mediation (Baron RM, Kenny DA. J Pers Soc Psychol 1986;51: 1173-82). Our primary aim was to determine
predicting factors of OSQOL scores. However, we added the interesting complementary analyses suggested by the reviewer.

(c) If really any moderation effects are to be tested, e.g. if physical activity changes boosts OSQOL regardless of BMI, then interaction terms should be entered into modelling (again, see Baron & Kenny, 1986). We have checked this point. The results are not suggestive of any interaction with physical activity (Please, see Table page 3 and the corresponding comments paragraph 1.3 above). In addition, we formally tested this interaction for each score (Wald test). Results were non significant: p=0.90, p=0.58, p=0.80, p=0.70 for dimensions 1, 2, 3 and 4, respectively.

2. Even though the authors acknowledge the limitations of the OSQOL-instrument in the two psychosocial domains, they should be even more cautious in their interpretations based on these dimensions: I dare to seriously doubt that the one item which indicates psychological state, i.e. “I feel very ill-at-ease”, has anything obesity-specific to it (making the interpretation of the threefold higher odds of the severely vs. the non-obese even more difficult, specifically in terms of poor QOL - which is not the same as depressive mood!). Also, is the item “I feel I am being attacked when people talk about my weight” really anywhere near sufficiency to assess overweight's impact on overweight people’s “Relations with others”? We acknowledge that this is a limitation of our approach. This noteworthy point has been mentioned in the Discussion section (limitations): “Domains referring to relations with others and psychological distress were only partially studied as only a single item was dedicated to these dimensions in the OSQOL. Given the prominent role of psychological welfare in QOL [ref], further studies with more elaborated instruments are needed to investigate these topics more accurately.”

3. Likewise, I strongly suggest a more balanced assessment of the pros and cons of pharmacy customers as a population among which to test the BMI-QOL-association among overweight adults. Besides that as noted above no response rate is reported (see also 10. below), a rather elderly, chronically (co)morbid, and possibly also acutely ill sample has resulted (when do you go to a pharmacy? – in case of need, if nothing else, isn’t it?). Unfortunately the rate of refusal was not documented. Our sample is not representative of the overall population of obese patients. Indeed, another aim of this study was to ascertain the cardiovascular risk level of overweight and obese patients. That is the reason why a sample of rather elderly patients with chronic conditions was targeted. It is noteworthy that the presence of chronic disease is common in this population. As a result, our results may be representative of a middle aged/elderly population of obese patients who often present chronic diseases.

This is not to say pharmacy customers are not an interesting population to study. However, a comparison of this sample with the French adult population or that of the Rhone-Alpes Region should be added to at least roughly assess how “representative of the overall population of overweight subjects” (p. 12) the sample is, especially given the present public health journal. As mentioned above, our sample cannot claim in any way to be representative of the general population of obese patients, even at a regional scale. An originality of this study was to show the feasibility of a pharmacy-based survey to investigate health issues and quality of life of obese patients. The corresponding paragraph (last one in the Discussion section) has been amended and extended as follows:

“An originality of the PRICARDO pharmacy-based study was its design. Studies on chronic diseases have been successfully conducted in pharmacies. Pharmacists with whom patients with chronic treatment have often built a relationship of confidence are ideally positioned to conduct such studies, notably in case of regular or chronic therapy. Our results proved the feasibility of such a study in the context of overweight and obesity. On the other hand, only a specific sub-population of obese patients is more likely to be easily captured in pharmacies: those needing a regular treatment.”

Of course, Major Compulsory Revisions should have significant impact on all sections, including Discussion and Conclusions.
Minor Essential Revisions

4. Abstract, Results, first sentence: This sentence is unclear: Affected by what? For higher clarity, we rephrased the sentence as follows: “QOL was inadequate for all dimensions in the 494 patients included in the study”

5. Abstract, Conclusions, first sentence: This statement is not justified by the results. It should read e.g. “Severe obesity impairs three of four dimensions of QOL”. This sentence has been removed from the abstract.

6. “Background”-section, first paragraph: This paragraph is too scanty. 2-3 sentences on QoL in chronic diseases, and 2-3 sentences on obesity should more thoroughly introduce readers to the paper.

   We have extensively reorganised the Background section into 3 main paragraphs: 1- obesity, 2- QOL issues, 3- The reasons to investigate QOL correlates in obese patients. The following sentences have been added with respect to QOL issues (notably with respect to chronic diseases):

   “Quality of life (QOL) gave rise to an ongoing interest these past years. QOL is a major tool to estimate patients’ perceived burden of diseases, for research purposes as well as for medical practice [ref]. It has become a common end-point in clinical trials, along with clinical outcomes. In the absence of perspective of recovery, QOL remains a useful criterion in the management of chronic diseases [ref].”

7. “Background”-section, third paragraph: Particularly because it introduces the central theme of the paper, this is both over-stated and under-cited.

   7.1- It’s over-stated because particularly (severe) obesity (rather than “excess weight in general”) may be (not “is”) detrimental for adults’ physical health-related QoL.

   7.2- It’s under-cited because the one study cited for mental health-related QoL (Dinc et al. 2006) on the one hand is rather specific (women in a Turkish city with a high obesity prevalence) and unrepresentative for Western Europe, and on the other hand virtually all of a huge number of studies have shown no noteworthy association between body mass and mental QoL. Not to refer to this is inadequate.

   We thank the reviewer for drawing our attention to these critical points. The sentence has been rephrased as follows: “Obesity may also have detrimental consequences on patients’ health-related QOL, particularly their physical functioning [Katz Corica Jia]. In contrast, the impact of obesity on mental components of QOL yielded more controversial conclusions [Katz Corica Jia Marchesini].”

We fully agree that the initial cited reference was awkward. It has been replaced by the following references:


8. “Background”-section, fourth and fifth paragraph: Have to be amended when changes according to Major Compulsory Revision 1. have been implemented.

As mentioned above, Background section has been extensively amended. The following sentence has been added: “We also investigated whether the relationship between OSQOL scores and BMI varied according to patients’ other characteristics.”

9. “Study design and population”-section:

How was the actual BMI of participants determined? As stated in the Limitations-section of the Discussion, “Only patients presenting a probable excess weight according to the pharmacist’s judgement were asked to participate” (which is critical, as the authors themselves state), but how was the actual BMI of participants assessed? BMI was collected in self-questionnaires from reported weight and height. Analyses excluded 25 patients with BMI below 28 kg/m². In actual conditions of practice it would have been too time-consuming for the pharmacist to compute the BMI himself/herself. In addition, some obese patients would not have felt at ease to be overtly asked their weight.

By measurement through the pharmacist or by self-report of the participants (given that it’s certainly not by estimation by the pharmacist). Also, the fact only patients presenting a probable excess weight according to the pharmacist’s judgement were asked to participate should already be mentioned in “Study design...”. Indeed, patients were selected according to pharmacists’ judgment. This point is mentioned in the corresponding paragraph:

“A survey was conducted in 2005 in 76 French community-based pharmacies of the Rhone-Alpes Region. A convenience sample of patients with probable excess weight visiting the study pharmacies were consecutively recruited and were asked to participate in the study.”

10. “Study design and population”-section: More information is needed:

(a) How were the instructions for the pharmacists on how to select those to be asked to participate among those with an estimated BMI >= 28?

Pharmacists were asked to propose the study to any patient with visible overweight and regular customers of the pharmacy (at least 12 months of drug dispensing recorded in the pharmacy). Patients who accepted to participate in the study completed self-questionnaires in which they mentioned their weight and height. Only patients whose BMI ≥ 28 kg/m² (based on the reported values) were considered for the analyses. The corresponding paragraph has been re-organised.

(b) How many pharmacy customers were asked to participate? I.e., how was the response rate? Unfortunately, refusals were not documented. However, as a prerequisite to participate was to be a regular customer, refusal rate may be assumed to be low.

(c) Why did recruitment stop at 551 patients? For reasons of funding? Considerations of statistical power? Other reasons. Initially, the aim was to recruit 600 patients: each investigator (n=75) was to include 8 patients. This number was purely empirical and not based on any power calculation. 579 patients completed self-questionnaires.

11. Re identification of co-morbid diagnoses, more information is needed as well: Which “drug therapies dispensed” were considered? Only those by the pharmacist recruiting the patient? Indeed, it was only drugs of the studied categories dispensed in the pharmacy during the past 12 months before inclusion. These data were obtained from computerised records of the Pharmacy. Nonetheless, only regular customers of pharmacies were included (and at least 12 months of medication recorded in the pharmacy) and most of them were treated for a chronic disease. Although the risk of missing any drugs dispensed in other pharmacies cannot be formally excluded, it may be expected to be low.

Only those dispensed at the visit within which recruitment took place? Any medications of studied categories dispensed to the patients within the 12 months preceding inclusion were taken into account, and not only inclusion visit.
12. Skewness is not a sufficient reason for dichotomizing quantitative scores for dimensions 1 and 2 (for instance, one could use transformations and conduct analyses of covariance). Indeed, normalization of these dimensions would have been desirable. However, transformations tested (log, square-root, square, exponential) did not permit to normalize the data, which led us to dichotomisation of the scores.

Also, further on in the text the authors do report results on the quantitative scores (p. 8, sentences 2 and 3). Thus, more justification is needed for dichotomization. Finally, choice of the lowest quartile has to be justified more substantively. We wanted to focus on the predicting factors of “poor” quality of life rather than a quality of life “lower than the median value” which may have been less specific. This led us to choose the 25% percentiles for quantitative scores instead of median value. This was an empirical compromise, as a more selective threshold could have resulted in a substantial loss of statistical power. This threshold enabled us to identify numerous correlates for these scores (Tables 3-5 of the revised manuscript).

13. p. 10, Discussion, third sentence: The items used to assess behaviours do not justify such a conclusion. We tend to disagree with the reviewer. Our results suggest that few patients endeavoured to make efforts in diet and physical activity to improve their health, which is in line with the conclusions of previous authors.

14. p. 10, Discussion, sentence after citation 19: This is incorrect: As reported in Table 4, moderately obese patients’ OSQOL did NOT significantly differ from those with BMI 28-29.9 – please do not overstate findings! We apologize this is a misunderstanding. We have rephrased the sentence as follows: “Patients’ QOL significantly decreased with severe obesity (BMI ≥ 35 g/m²) for 3 dimensions of the OSQOL questionnaire (Table 5).”

15. Tables:

(a) Table 1: More information on age distribution should be given in the text (range etc.) Age (mean=62) ranged from 27 to 86 (25th-75th percentiles: 54-72). As a consequence our sample mainly consisted of middle aged /elderly overweight and obese patients. The range and the median age were already mentioned. 25-75th percentiles have been added in the revised version (Results section).

(b) Missing data has a dash (“-”) under “Social economic status”. This should be deleted, and “Social economic status” should be changed into “Socio-economic status”. We apologize for this typo that we have corrected.

(c) Tables 1, 3 + 4: In BMI-categories, “< 30” should be “28-29.9”, and “[30 – 35]” should be “30 – 34.9”. We have corrected these points in the different tables. We have also made the same changes for age categories.

(d) Tables 1, 3 + 4: Given that the “Three and more”-number of co-morbid diagnoses–group (which by the way should read “Three or more”- thank you for noticing this point that we have corrected.) comprises almost 60% of the sample, a finer-grained analysis should be possible here (e.g. “0-1”, “2”, “3”, “4 or more”). We have recomputed the statistical relationship between OSQOL scores and the number of co-morbid diagnoses with the more detailed stratification suggested by the reviewer. The results suggested that no major changes were observed after detailing this category (Table below for information). Physical dimension noticeably decreased in case of > 2 co-morbid diagnoses with no real further impairment beyond this threshold. Similar conclusions can be reached for vitality, while the other two dimensions remain non significant. The corresponding paragraph in the result section has been amended as follows:

“Finally, the number of co-morbid diagnoses had a significant impact on physical functioning and vitality dimensions, notably beyond two associated diagnoses (Table 3). When the category “3 or more co-morbid diagnoses” was detailed into “3” and “4 or more”, these conclusions were not affected (data not shown).”
OSQOL scores and according to co-morbid diagnoses (Compared results)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Dimension 1</th>
<th>Dimension 2: Vitality desire to do things</th>
<th>Dimension 3: Relations with others *</th>
<th>Dimension 4: Psychological state **</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>% patients ≤ Q1 score *</td>
<td>% patients ≤ Q1 score *</td>
<td>% 'Fairly true' or 'absolutely true'</td>
</tr>
<tr>
<td>Overall</td>
<td>494</td>
<td>25.1</td>
<td>27.9</td>
<td>19.6</td>
</tr>
<tr>
<td>Number of associated co-morbid diagnoses</td>
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<td>17.9</td>
<td>24.4</td>
<td>16.7</td>
</tr>
<tr>
<td>Two</td>
<td>127</td>
<td>18.9</td>
<td>19.7</td>
<td>17.3</td>
</tr>
<tr>
<td>Three or more</td>
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<td>32.5</td>
<td>21.4</td>
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<tr>
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<tr>
<td>None or one</td>
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<td>17.9</td>
<td>24.4</td>
<td>16.7</td>
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<td>Two</td>
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<td>30.2</td>
<td>32.9</td>
<td>24.2</td>
</tr>
<tr>
<td>Four or more</td>
<td>140</td>
<td>29.3</td>
<td>32.1</td>
<td>18.6</td>
</tr>
</tbody>
</table>

Also, that the present study does not use a severity-adjusted comorbidity index has to be justified. We acknowledge that a co-morbidity index would have been helpful in the present study.

Discretionary Revisions

16. Keywords: Behavioral factors are missing from this list; also, “gender” is critical as a KEYword since analyses that would “really” be gender-sensitive would have been stratified for gender, and would have examined interaction terms with other variables.

We thank the reviewer for this suggestion this key-word has been added in the list. We tested the interaction of gender on the relationship between BMI and the different OSQOL scores. The results were non significant: p=0.14, p=0.99, p=0.50, p=0.95 for dimensions 1, 2, 3 and 4, respectively.

17. “Background”-section, second paragraph, first sentence: Why only one citation, and why only for older adults?

The following reference has been added:


18. Why were the items regarding previous efforts to change diet and physical activity restricted to changes aiming at health improvement? people may change for other reasons as well. We
acknowledge that this was a limitation of our approach. We wanted to focus on positive changes to improve health. Nonetheless, it could be assumed that in this population, changes toward better dietary and exercising habits may be at least in part driven by health concerns in addition to better physical shape.

19. Please justify why p < .10 instead of p < .05 was used as criterion to include covariates other than gender, BMI and socio-economic status. In epidemiology it is common to use p<0.10 or even higher values (up to 0.20) in order not to miss any potential confounding factors (Bouyer, 1996). Reference: J. Bouyer / Epidemiologie quantitative Ed INSERM Paris

20. Information of the total sample size (551) and of those who had completed all OSQOL-dimensions (494) are probably better placed under Methods than under Results. This would have been an excellent idea. However, we also compared the 494 patients with those of their 551-494 counterparts. Only for this reason, we believe that this part is more appropriately located in the Result section.

21. Under Analyses (p. 6), the information of dichotomization and using quartiles is unneeded since this has been explained under Date collected (p. 5) already. We thank the reviewer for drawing our attention to this point. The redundant sentences have been removed. We judged this paragraph more appropriate in the ‘analyses’ sub-section.

22. p. 8, line 3 under 3-Univariate correlates: This should be “(Table 4)”. Table 3 refers to univariate results while table 4 comprises analyses for regressions in the former version. Please, note that table numbers have changed in the revised version given the insertion of an additional one.

23. p. 12, sentence ending with citation 28: This argument also holds for the operationalization of physical activity. In other words, “retrospective self-report” as a critical feature may contribute to possibly falsely significant results as well as possibly falsely insignificant results, and should not be used as an argument in the latter case only.

Indeed more caution is desirable with respect to interpretation of these results, as suggested by the reviewer. We have removed the corresponding sentences and, as remain more cautious, the more so as this point had already been addressed in the paragraph pertaining to study limitations. We have slightly rephrased the sentence on a more appropriate way as follows: “All data collected on questionnaires about the patients were purely self-reported and the data obtained for reported physical activity and dietary habits should therefore be interpreted cautiously. Further investigations with more accurate assessments of patients’ lifestyle should be needed for more conclusive results”

24. p. 14, last sentence before “Conclusions”: I do not see how the assertion that pharmacists may “greatly contribute to the preventions of excess weight” relates to a study in which all participants already are of excess weight. The conclusion has been amended as follows: “In conclusion, this survey has proved that the consequences of excess weight on patients’ lives can be evaluated by studies performed in community-based pharmacies, as already experimented for other chronic diseases. Factors such as age, gender, dietary habits, physical activity or socioeconomic level should be taken into account by care-givers before interpreting QOL in overweight and obese patients.”

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

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.