Author's response to reviews

Title: Income and Patient-Reported Outcomes (PROs) after Knee Arthroplasty

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Author's response to reviews: see over
We thank the reviewers for their comments. Following are our point-by-point responses to their comments:

Reviewer 1:
It is my pleasure to review the manuscript entitled, “Income and Patient-Reported Outcomes (PROs) after Total Knee Arthroplasty in the U.S.”

This is a well written and well described paper. My concern is that the findings that low income is associated with less pain but greater dysfunction are not compatible and the findings may simply be spurious.

Response: We thank the reviewer for kind comments.

Minor comments:

Title: do the authors believe their findings from a single institution can be generalized to the entire US? I think the title should be amended.

Response: We have amended the title as suggested, it reads as “Income and Patient-Reported Outcomes (PROs) after Total Knee Arthroplasty”

Abstract: this line should be edited as the findings are certainly different, At 5-years, numerically similar but non-significant odds were noted”

Response: We have modified this sentence as “At 5-years, odds were not non-significantly different.”

Intro: The authors write, “Much emphasis in the previous studies has been placed on implant and surgical aspects of arthroplasty, with very few studies focusing on patient demographics, medical comorbidities and socioeconomic predictors.” However there is a plethora of literature looking at demographic predictors of TKA outcomes including age, gender, obesity etc.

Response: We have modified this sentence as suggested to “Much emphasis in the previous studies has been placed on implant and surgical aspects of arthroplasty and its demographic predictors, with very few studies focusing on socioeconomic predictors.”

I’m curious to know why the authors had the a priori hypothesis of “but more improvement in function outcomes with TKA compared to preoperative scores.” When the authors state there isn’t any previous literature to guide this.

Response: The literature in this area is scarce. This hypothesis was based on one previous TKA study quoted at the beginning to this paragraph in introduction that suggested that
improvements are greater in the lower income group. “To our knowledge, there is only one study in TKA cohort (18). This study found no differences in pain and function outcomes 2-years after TKA by income level, but higher gains in lower income group (18).”

The methods describe the dataset collecting complications. I think it should be included in this manuscript for the reader to understand the risks and benefits of income on TKA.

Response: We agree with reviewer's excellent suggestion that exploring the impact of income on complications would be an important question to pursue. This would require support from additional financial resources/grants for data programming and analyses, as well as ethics review board approval. We plan to explore this for a future paper, since this is outside the scope of the current paper and we do not have financial resources to do these analyses at present.

Is the Mayo knee questionnaire been validated for use in this population? I don't believe the reference given supports this.

Response: We agree that quoted reference only provides data on inter-observer reliability, and we have made this correction. The Mayo questionnaire is based on the American knee society score, a validated, most commonly used assessment tool. The pain and function questions analyzed are the same as in knee society scale – “Mayo Knee pain and function questionnaires (24) shown to be reliable, is based on the American Knee society scale, a validated instrument that is most commonly used evaluation of knee arthroplasty patients (25-27). The pain and function questions analyzed in this study are same as those in the Knee Society Score (28).”

Is it necessary to adjust for both ASA and comorbidity? Do the authors find any colinearlity between these two variables?

Response: We tested for collinearity between the two variables, and found it to be low, Spearman’s correlation coefficient of 0.33. Our a priori cut-off for collinearity was 0.5. Therefore, the analyses were adjusted for both variables, since they seem to capture slightly different domains of health.

I find the results confusing. How did the authors determine that low income was associated with greater improvement in knee function?

Response: This interpretation was based on one of the outcomes that examined the change in knee function improvement with response to the following question “Compared to your condition before your knee surgery, how would you rate your knee function?” In fact this finding in our study is similar to a finding of more improvement in TKA patients with lower income and because lower income patients start with much worse preoperative function and
therefore have higher likelihood of greater improvement.

“To our knowledge, there is only one study in TKA cohort (18). This study found no differences in pain and function outcomes 2-years after TKA by income level, but higher gains in lower income group (18).”

“Another interesting finding from our study was that patients in the lowest income category were twice more likely than those in the highest income category to report ‘better’ improvement in the index knee function 2-years after primary TKA. This finding should not be surprising at all, considering that those in the lower income categories have worse preoperative functional status (18, 20, 49), but similar postoperative function after TKA (18, 49), than those in the higher categories.”

**Why are all the outcomes categorical when the vast majority of TKA literature uses continuous outcome scores? Can the authors use continuous measures for outcomes?**

Response: We agree that several other outcome instruments have continuous outcomes. The outcomes in our study are based on categorical outcomes. We do not have additional continuous outcome scales that were co-administered to the patients.

**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  Title: Income and Patient-Reported Outcomes (PROs) after Knee Arthroplasty in the U.S.

Version: 1 Date: 8 October 2012

Reviewer: Hassan Ghomrawi

Reviewer's report: a file was attached

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I have no competing interests

For: BMC Medicine

By: Hassan Ghomrawi

1. Is the question posed by the authors new and well defined?

The authors seek to determine the effect of income on patient-reported outcomes at 2 and 5 years post-total knee replacement. There is a paucity of literature addressing the effect of income on total joint arthroplasty outcomes; thus the novelty of the question posed by the authors. The question is well defined and the authors clearly state their hypothesis towards the end of the introduction section.

Response: Thanks.

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?

To address the research question, the authors utilize data from the Mayo Total Joint Registry, one of the largest US joint registries. The authors implement a cohort study design and identify 2 cohorts for the 2 year and 5 year analyses. The predictor and outcome variables are clearly stated with enough detail to replicate the work. The authors use logistic regression to assess the impact of income on patient reported outcomes.

Response: Thanks.

3. Are the data sound and well controlled?

The authors utilize baseline demographic and clinical data on patients and state on page 5 that “Validated Mayo Knee pain and function questionnaires (24) have been administered to all patients undergoing knee arthroplasty and these data have been captured electronically starting in 1993.”
The reviewer is unclear as to whether this information was captured at baseline and if so why it was not included in the analysis. The authors also do not acknowledge this as a limitation in the discussion. There is solid evidence that preoperative pain and function are strong predictors of postoperative patient-reported pain and function. In fact the only study the authors cite (ref 18 by Davis et al.) that studies this phenomenon and finds no effect of income controls for preoperative function and pain. In this study also, there is a much weaker association with the change variables than with the state variables.

Response: We agree this is a limitation of the analyses and have included it in the limitations section. This was done for two reasons: (1) non-response at baseline and follow-up led to a much smaller sample, which would have even greater issues with generalizability; and (2) as opposed to other studies, that do not have a change variable, our questionnaires included a “change” question. Therefore, a decision was made a priori to not additionally adjust for preoperative variables, to allow a large enough sample size to detect meaningful differences and allow for results to be more generalizable.

“Preoperative function was not included in the model, a limitation of the current analyses. However this was done, since this would further limit the sample size due to an increase in the non-response bias, further limiting the generalizability. In addition, we had a “change in function” variable that was clinically meaningful to the patients and therefore baseline function was not needed to create a surrogate variable for change in function.”

2-There is clear response bias in results as clearly indicated by the authors in the results section (page 7). In fact, non-responders differed from responders on almost all the baseline variables examined that one questions the generalizability of these results. This may be the result of Mayo being a referral center which attracts patients from all over the US and from overseas.

Response: We agree non-responders differ from responders and discuss this as the first limitation in the limitations section.

Given the wide geographic variations in income level, an income of $45,000 may have more purchasing power in Minnesota than in New York city. One approach to this problem is to restrict the analysis to individuals who live in the mid-west.

Response: We agree that same income can mean different things for people living in different parts of the U.S. As suggested by the reviewer, we have added this to the discussion. Income categories were chosen based on previous studies with $35K being twice the poverty income for a family of four in 2003-2005. We believe that limiting the analyses to a region would limit the sample size (one of main strengths of the study over a previously negative study) and limit the generalizability of the study results significantly. We agree and recognize the income differential issues in discussion. Our study has fewer issues in this regards, considering that a previously published study was an international study, where these issues are much larger.

“People with the same income in different parts of the U.S. (New York versus Mid-west versus
South) have slightly different purchasing power. Although this does not impact the observed associations, it may reflect slight differences in socio-economic status.”

Nowhere in the article do the authors mention how many patients were in each of the income categories. This information needs to be included to have a clear understanding of the characteristics of the predictor of interest. Additionally, although the authors have successfully used the income categories in other published studies, there needs to be a justification of these categories for the purposes of this specific study.

Response: We have added the number of patients in each income category in table 1 as suggested. There were 23%, 44% and 33% at 2-years and 31%, 42% and 27% at 5-year follow with <=35K, >35-45K and >45K income respectively. We now provide detailed rationale for income categories as follows:

“Categories were made based on the fact that $35,000 was twice the poverty level income for a family of four in 2003-2005 and the category of >45,000 represented those with above median U.S. household income during the study period, since the median household income ranged $43-45,000 from 2000-2003 (31).”

4. Does the manuscript adhere to the relevant standards for reporting and data deposition? Yes

5. Are the discussion and conclusions well balanced and adequately supported by the data?

Response: Thanks.

The authors mention that a lack of significant association with the 5 year outcomes may be due to smaller sample size. The reviewer is perplexed by this statement as the authors have more than 4000 patients for the 5-year follow up.

Response: We agree and have corrected this as recommended, it reads as “Similar, but non-significant, associations were noted at 5-years.” Several study findings merit further discussion, but need to be interpreted considering study limitations.

The second paragraph on page 9 discusses activity limitation in relation to the contralateral knee or hip joint. This argument is not supported by the results and should not be in the discussion section.

Response: As recommended, we have removed references to contralateral hip and knee joint and have only left in the statements supported by published literature.

“We also found that overall moderate-severe activity limitation was higher in lower income
categories, not unexpected given that activity limitation depends not only on index knee, but other extremity joints. Lower income is associated with worse osteoarthritis (50) and greater need for TKA (18). Lower income is also associated with higher postoperative complication rate (14, 19).”

The limitations section in the discussion is very brief and many of the limitations of this study are “delayed” till the end and should be stated upfront in the methods section.

Response: We agree and have moved this to the top of the discussion --“Several study findings merit further discussion, but need to be interpreted considering study limitations.”

6. Do the title and abstract accurately convey what has been found? Yes. 7. Is the writing acceptable? Yes.

Response: Thanks.

Editor’s comments

Please also ensure that your revised manuscript conforms to the journal style (http://www.biomedcentral.com/info/ifora/medicine_journals). It is important that your files are correctly formatted. Specifically, please address the following editorial concerns:

1) Competing interests and Acknowledgements

Please move these sections from the title page to after your Conclusions section.

Response: We agree and have moved these sections as recommended.

2) IRB

Please move the IRB information from the title page to your methods section

Response: We agree and have removed this section as recommended.

3) Significance and Innovation

Please remove this section (currently after the abstract)

Response: We agree and have removed this section as recommended.