Author's response to reviews

Title: Data enhancement for co-morbidity measurement among patients referred for sleep diagnostic testing: an observational study

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Author's response to reviews: see over
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Dear: BMC Medical Research Methodology Editorial Board Members:

Thank you for having our manuscript entitled “Data Enhancement for Co-morbidity Measurement Among Patients Referred for Sleep Diagnostic Testing: an Observational Study” (MS: 9523080872587690) considered for publication in BMC Medical Research Methodology. We found the reviewer’s comments insightful and feel that our revised manuscript has been improved through the peer review process. Please find below a point-by-point response to each of the reviewer’s comments. We have highlighted all new or revised text in the manuscript using blue text. In addition, we have appended the changes below each of the comments to facilitate your review.

Reviewer #1:
1. One minor point to be addressed in the Background section. There are more recent references available for the statements in the first paragraph. Current population OSA prevalence data estimate the ratio of females to males to be more similar, although the discrepancy continues to be pronounced in sleep clinic samples. The references for cardiovascular co-morbidities are numerous, so the two cited should be considered examples.

We agree with the reviewer that more recent references should be used for OSA population estimates. Based on a recent review article by Punjabi et al (Proc Am Thorac 2008;5:136-43) three additional references have been added to show the current prevalence estimates to be more similar between males and females. These include:


The background paragraph on page 4 now reads:
“Population-based studies estimate the prevalence of OSA to be approximately 3 to 7% for adult males and 2 to 5% for adult females in the general population [1-4]. Furthermore…”

Additional references have also been added for each co-morbid condition associated with OSA. These include:


2. Minor essential revision (clarification): The definition of “enhanced co-morbidities” should be spelled out more clearly, as does the authors’ position on the best method to ensure accuracy. The concept and importance of stratifying by OSA severity is clear, however after several re-readings, I interpreted the findings to mean that in no case did the combining of all sources of information enhance accuracy, but either information source, combined with the severity stratification most accurately reflects co-morbidity prevalence. However, this was not directly demonstrated in Results. In fact, it looks as if combining data sources would be expected to decrease accuracy. The last sentence, 1st paragraph in Discussion: “These results suggest that both data sources should be used if possible when defining co-morbidity in OSA patients, as use of either source alone will result in an underestimate of the prevalence of these conditions” as well as the 1st sentence of Conclusions: “We found that administrative data in combination with survey data has the potential to create a more complete measure of the co-morbidity among patients referred for sleep diagnostic testing” maintains my confusion on this point.

We agree with the reviewer’s comments and have added text to the discussion section to clarify our position on the best method to ensure accuracy. It is true that we did not directly validate the accuracy of the combined methodology. We acknowledge this as a limitation in the discussion (page 15). This study
employed an indirect measure of accuracy under the assumption that as OSA severity increases, the prevalence of co-morbid conditions also increase. As mentioned, these trends observed are consistent with what has been shown in the literature and thus provides face validity for our study findings. The reviewer is also correct in that accuracy of co-morbidity was not increased for all conditions of interest. We have modified text in the discussion and conclusion section to explain how using a combination of sources can increase accuracy in situations where agreement between administrative data and self-report is poor.

The following text has been added to the discussion section on page 13: "These results suggest that when agreement between data sources is poor, a combination of sources should be used when defining co-morbidity in OSA patients, as use of either source alone may result in an underestimate of the prevalence of these conditions. Specifically, using “either” self-report or administrative measure will increase the sensitivity of the estimate of co-morbidity”.

The conclusion on page 15-16 now reads: “We found that administrative data in combination with survey data has the potential to create a more complete measure of the co-morbidity among patients referred for sleep diagnostic testing, particularly when agreement between survey and administrative data is poor. Given the resources required to obtain clinical data, use of data enhancement with administrative data may be valuable to other researchers. Although, future studies are required to validate co-morbidities based on data enhancement, these results suggest that this methodology can aid in the adjustment of these coexisting conditions in observational studies in this area”.

3. The important new findings about data enhancement emerging from this study should be clearly identified in the Discussion. Implications of the present findings for past studies of this type, and suggestions for improving future research should be clearly stated in the Conclusions section.

We have outlined the important findings about data enhancement in the discussion section on page 12. Implications and suggestions for future research are stated in the conclusion on page 15-16. (See revised conclusion in response to reviewer's second comment above).
Reviewer #2:

P4 L2 – “…there have been no studies to date…” The investigators should better develop their study rationale. A large volume of the literature was not cited! They should cite a series of pivotal reports from Manitoba, Canada (from MH Kryger’s group) and Israel (A. Tarasiuk’s group), which, by using administrative economic databases, explored OSA morbidity years prior to diagnosis among different populations.

We have added references from the following research groups and have modified the background text on page 5 to read as follows:

“Previous studies have assessed co-morbidity in OSA patients in the years prior to diagnosis [34, 35]. However, many of these studies have relied on administrative records alone to determine co-morbidity. This source alone may result in an underestimate of co-morbidity within these populations. Given the importance of co-morbidity in observational studies of OSA patients…”

P4 2nd paragraph – It is not clear how the use of “…administrative databases” will “…enhance self-reported co-morbidity”. Please clarify your study aim.

The aim has been clarified as requested on page 5 and has also been changed in the abstract on page 2.

“…the purpose of this study was to evaluate whether the combination of administrative data and self-reported data provided a more complete estimate of co-morbidity among patients referred for sleep diagnostic testing.”

P5 last two lines – Please change RDI to Apnea-Hypopnea Index (AHI). Please include in the text a brief description of your methodology of scoring AHI.

Our study employed both ambulatory monitoring and polysomnography to classify OSA severity. The ambulatory monitor (Remmers Sleep recorder) employs an automated analysis algorithm that analyzes the shape of the desaturation profile in order to determine a respiratory event. Unfortunately, this algorithm does not distinguish between apneas and hypopneas and thus a hypopnea definition was restricted to only those patients who underwent polysomnography. As such, summary statistics of the RDI were really a composite of the polysomnographically derived AHI and the ambulatory monitor derived RDI.

We have demonstrated in previous papers that the bias between RDI and AHI is minimal (Vazquez et al, Thorax 2000). Given that previous validation studies have employed the term RDI, we preferred to stick to the term for consistency.

We have added the following sentences to describe the RDI scoring methodology on pages 6 and 7: “The RDI was defined as the number of apneas and hypopneas
Apnea was defined as a cessation of airflow for at least 10 seconds. Hypopnea was defined as an abnormal respiratory event lasting 10 seconds or more, with at least a 30% reduction in thoracoabdominal movement or airflow compared to baseline, and associated with at least a 4% oxygen desaturation. OSA severity categories included...

P6 “Determination of Co-morbidities and Clinical” 1. How did you control for the quality of data collected? 2. Was there a technician available to clarify questions? 3. Please provide reference regarding the validity and/or psychometric properties of questionnaires used.

Given the purpose of the questionnaire, to collect basic demographic data and information on co-morbidities, we designed our questionnaire based on standardized national surveys (Canadian Community Health Survey Cycle 1.1) and thus did not validate the questionnaire. Furthermore, psychometric properties of this questionnaire are unavailable. A technician was available to clarify questions and was responsible for collecting the medication data for each patient. An additional line has been added to page 7 regarding co-morbid and clinical data collection: “Patients were also required to provide a list of their current medications at the time of the survey”.

P6 “Determination of Co-morbidities from Administrative Data Sources” For those of us who are not familiar with the Alberta health system, what is the validity of these administrative databases? Was the validity confirmed in previous studies, similarly to that of the Manitoba database (in many studies)? Please provide references to support your findings.

Unfortunately, there are no studies that have directly validated the Alberta administrative databases. However, given the similarities in funding and administration of health services by province across Canada, there is no reason to believe the validity of the Alberta data sources is any different than those in Manitoba.

P6 2nd paragraph – give reference to Epworth Sleepiness Scale (Johns, Sleep 1991;14:540-554).

Thank you for the suggestion, the reference has been added.

P13 1st paragraph – the authors should include in this paragraph some discussion of why agreement was also low for stroke. Clearly the diagnosis of stroke is traumatic to both patients and families, and they are aware of it!

We agree that this is a very interesting finding given the traumatic nature of stroke. We speculate that the discrepancies between administrative data and self-report for identifying stroke are due to the lower sensitivity of the administrative
algorithm (67%). Thus, underestimating the true prevalence. The following text has been added to page 14:

“The poor agreement between the two sources for stroke was also an interesting finding. We speculate that the discrepancies between administrative data and self-report for identifying stroke are due to the lower sensitivity of the administrative algorithm (67%), thus underestimating the true prevalence within this source. Again, the combination of either source likely provides a more accurate representation of stroke prevalence in this clinical population”.

Editorial Comment:

Please clarify if informed consent was obtained. As the study is retrospective we assume not, but we would appreciate if you could let us know the ethical circumstances for data collection (e.g. was cleared by ethical review board).

We have clarified on page 7 that informed consent was obtained for this project. The statement reads: “This study was approved by the Ethics Review Board of the University of Calgary”.

We hope that we have satisfactorily addressed your comments and thank you in advance for your further consideration.

Sincerely,

[Brenda Hemmelgarn MD PhD FRCPC]