ARIC Manuscript Proposal #755S

SHHS Manuscript Proposal

1. **a. Full Title:** Predictive Factors for the Presence of Nocturnal Heartburn in Patients with Obstructive Sleep Apnea (OSA)- The Sleep Heart Health Study (SHHS)
   
   **b. Abbreviated Title:** Heartburn in Patients with OSA

2. **Lead Author:** Ronnie Fass
   
   **Writing Group:** Stuart F. Quan plus others to be nominated

3. **Timeline [Target start and finish dates, assuming P&P approval and Coordinating Center availability for analysis]:** Analysis can begin from time of project’s approval.

4. **Rationale:**

   Gastroesophageal reflux disease (GERD) has been suggested to be commonly present in patients with sleep apnea (1,2). The exact relationship between the two disorders remains unclear. GERD and OSA are common in obese patients and may co-exist as two separate disorders (3). On the other hand, GERD may cause respiratory symptoms through micro-aspirations and thus may lead to OSA (4). However, OSA may precipitate acid reflux, by reducing intra-thoracic pressure during apneic episodes. Studies attempting to establish a casual relationship between the esophageal acid reflux events and OSA, relying mostly on 24-hour esophageal PH monitoring measurement, have been inconclusive (4). Less than a handful of studies showed no temporal relationship (3,5). The SHHS provides a unique opportunity of assessing a large number of OSA patients. The study included a specific question about heartburn and indigestion during awakening from sleep. Reports of heartburn during awakening from sleep by OSA patients are by far regarded as the symptom that mostly suggests a close relationship between GERD and OSA.

5. **Hypotheses:** 1. Nocturnal heartburn is common in patients with OSA. 2. There will be a close correlation between heartburn frequency and severity of OSA (sleep and pulmonary parameters). 3. There might be predicting factors (sleep and pulmonary parameters) for the presence of GERD between OSA patients with and those without nocturnal heartburn.

6. **Data [variables, time window, source, inclusion/exclusion]:** SHHS data, sleep study and PFT’s of all participants.

7. **Type of Study:** Cross-Sectional analysis of data from all SHHS sites using SHHS Sleep Habits Questionnaire (particularly Q18G), demographic information, RDI4%, %O2<90%, sleep architecture variables.

8. **Type of Publication:** Journal article
Target Journal:  Internal Medicine or Gastroenterology

9. Analysis Responsibility:  Central

10. Introduction:  Using data from SHHS will provide a great opportunity to describe the distribution of nocturnal heartburn in OSA patients and correlate the presence or absence of GERD symptoms to the severity of OSA.

11. Independent Variables:  Heartburn (Q18G--Sleep Habits Questionnaire), RDI4%
   Dependent Variables:  RDI4%, heartburn
   Covariates:  Age, gender, sleepiness scale score, snoring status, years of education, body mass index, alcohol drinking, smoking status, sleep symptoms
   Stratification:  By the presence or absence of heartburn or indigestion
   Analysis Techniques:  Chi square, logistic regression, multiple linear regression

12. Summary section:  The result of this study will enable us to further explore the relationship between GERD and OSA. Most of the studies thus far included a relatively small number of subjects. In addition, this report will determine if there is any correlation between disease severity of OSA and severity of GERD symptoms as well as possible predictive factors for the presence of GERD.

13. References: