SHHS MANUSCRIPT PROPOSAL

1. FULL TITLE: Longitudinal Evaluation of Sleep-Disordered Breathing, Sleep Symptoms, and Quality of Life in the Sleep Heart Health Study.

ABBREVIATED TITLE: Longitudinal Evaluation of SDB, Symptoms and QoL.

2. PROPOSED WRITING GROUP MEMBERS:
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3. TIMELINE [TARGET START AND FINISH DATES]
Analysis of data can begin immediately. An abstract for presentation at APSS in 2007 will be submitted during the Fall 2006 call for abstracts. Analyses and a preliminary draft of the paper will be completed by October 2006.

4. RATIONALE:
The association between sleep-disordered breathing (SDB) and reduced quality of life (QoL) has been shown in several studies.[1-3] Published data from the first evaluation of the Sleep Heart Health Study (SHHS) demonstrated a cross-sectional relation between severe SDB, difficulty initiating and maintaining sleep (DIMS), and excessive daytime sleepiness (EDS) with reduced SF-36 QoL scales.[4] Short-term longitudinal studies assessing changes in QoL among subjects with SDB have shown improvement in the subject's QoL after treatment.[5-7] Longitudinal changes in SDB and sleep related symptoms and their association with QoL in a community population have yet to be evaluated.

This study will assess changes in SDB and sleep symptoms and their association with QoL of participants in the first and second SHHS evaluations.

5. HYPOTHESES

1) QoL will decrease in subjects who are identified as having SDB, DIMS, and EDS from the first to the second SHHS evaluations, and QoL scores will improve for subjects whose SDB scores improve.

2) QoL scores will decrease for participants who maintain their SDB status from the first to the second SHHS evaluations, or whose SDB, DIMS, or EDS scores increase (poorer SDB/sleep outcome).

6. DATA [VARIABLES, TIME WINDOW, SOURCE, INCLUSIONS/EXCLUSIONS]

The main independent variables will be SDB, DIMS, and EDS. The change in these variables from the first to the second SHHS evaluation will be compared. Preliminary analysis suggests that the mean for respiratory distress index ≥ 5 at 4% desaturation is higher (worse) for SHHS2 than SHHS1 (18.6% vs 17.75%). The association of changes in SDB, DIMS, and EDS scores with QoL scales will also be assessed. Covariates to be

included are age, gender, ethnicity, education, marital status, body mass index (BMI), smoking, sleep medication, cardiovascular and respiratory problems, and diabetes. All participants from SHHS1 and SHHS2 who completed the Sleep Habits Questionnaire (SHQ), QoL Medical Outcomes Survey (MOS) SF-36, and polysomnography (PSG) will be included in the analysis.

7. TYPE OF STUDY: Secondary, data from all sites

8. TYPE OF PUBLICATION: ABSTRACT: Associated Sleep Professional Societies or the American Thoracic Society. MANUSCRIPT: Peer-Reviewed Journal.

TARGET JOURNAL: SLEEP

9. ANALYSIS RESPONSIBILITY: Local

10. BRIEF ANALYSIS PLAN [include list of variables to be used, time frame of data, source of non-SHHS data, and probable statistical methods]

The proposed analysis will examine the longitudinal association between SDB, DIMS, and EDS on change in QoL scores.

INDEPENDENT VARIABLES: SDB, DIMS, and EDS.

DEPENDENT VARIABLES: SF-36 QoL scales.

COVARIATES: age, gender, ethnicity, education, marital status, BMI, smoking, sleep medication, self-reported diabetes, and cardiovascular and respiratory illnesses.

PROBABLE STATISTICAL METHODS: Chi-square, paired t-test, linear or logistic regressions, multivariate mixed-effects logistic regression models.

Initial analyses will be performed utilizing continuous variables. Variables will also be categorized and assessed for associations. The respiratory distress index based on a 4% oxygen desaturation (RDI 4%), calculated as the number of apneas plus hypopneas per hour of total sleep time will be categorized into <5, 5 - <15, ≥15 - <30 and ≥30. Severe SDB will be defined, as in previous SHHS analyses[8], as an RDI 4% ≥ 30.

The scores for DIMS and EDS will be assessed using the SHQ. These scores will be dichotomized at appropriate values to represent normal and abnormal values.

Each of the QoL measures will be assessed and dichotomized at specific distributions if necessary. The SF-36 scales include the 1) physical activities, 2) social activities; 3) physical health problems; 4) bodily pain; 5) general mental health; 6) vitality; 7) general health perceptions, and 8) role emotional.

Potential confounding variables, including age, gender, ethnicity, education, marital status, and body mass index (BMI) will be evaluated.

1) Initial analyses comparing the demographic and other distribution for participants in SHHS1 and SHH2 will performed using chi-squared and paired t-tests.

2) The scores for SDB, DIMS, and EDS will be assessed for change from SHHS1 to SHHS2. Analyses comparing concordant and discordant pairs to QoL measures will be performed, giving emphasis to the discordant pairs.

3) Separate multivariate logistic regression models or if appropriate, multivariate mixed-effects logistic regression models will be fitted independently to each of the QoL measures to assess association with SDB, DIMS, and EDS, adjusting for potential confounders. Centers and subjects will be included as random effects to account for center effect and serial intra-subject correlation of repeated observations.

4) Finally, the effects of time varying covariates will also be assessed (i.e., education, marital status, BMI, smoking, sleep medications, as well as cardiovascular and respiratory illnesses and diabetes).

11. REFERENCES

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4. Baldwin CM, Griffith KA, Nieto FJ, O'Connor GT, Walsleben JA, Redline S. The association of sleep-disordered breathing and sleep symptoms with quality of life in the Sleep Heart Health Study. Sleep 2001;24(1):96-105.
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6. Lloberes P, Marti S, Sampol G, et al. Predictive factors of quality-of-life improvement and continuous positive airway pressure use in patients with sleep apnea-hypopnea syndrome: study at 1 year. Chest 2004;126(4):1241-7.
7. Parish JM, Lyng PJ. Quality of life in bed partners of patients with obstructive sleep apnea or hypopnea after treatment with continuous positive airway pressure. Chest 2003;124(3):942-7.
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