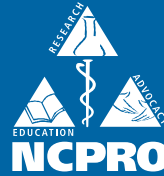


The National Center for the Promotion of Research in Otolaryngology invites otolaryngology practices to participate in a prospective outcomes study of adults to evaluate the effectiveness of uvulopalatopharyngoplasty (UPPP) in improving sleep apnea-related quality of life and symptoms.

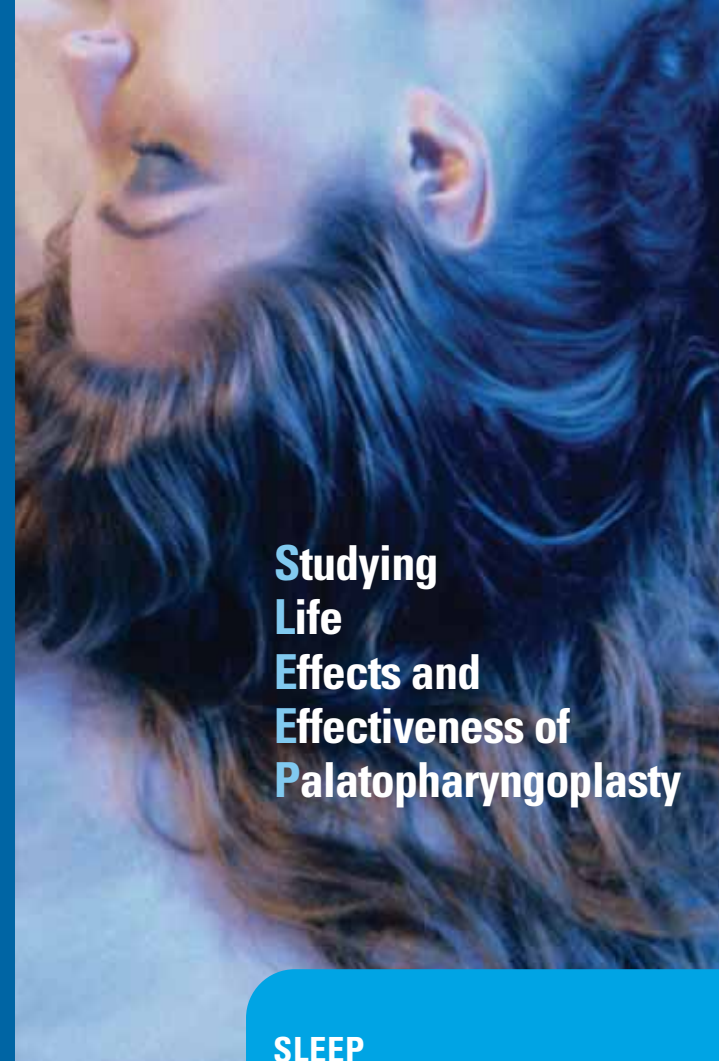
The SLEEP study is based upon patient and physician questionnaires. The investigation affords the practicing physician an opportunity to actively engage in research directly related to improving patient care.



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Studying Life Effects and Effectiveness of Palatopharyngoplasty

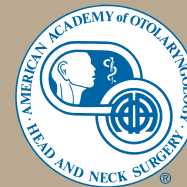
SLEEP

Sponsored by the American Academy of Otolaryngology—Head and Neck Surgery Foundation, and its National Center for the Promotion of Research in Otolaryngology. Supported in part by a generous unrestricted educational grant from Schering-Plough. This research is coordinated at the Duke Clinical Research Institute at Duke University Medical Center in Durham, North Carolina.



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Studying Life Effects and Effectiveness of Palatopharyngoplasty

Specific Study Aims

Adults 18+

- To determine** whether UPPP improves sleep-related quality of life, measured on *Functional Outcomes of Sleep Questionnaire*
- To establish** whether UPPP affects sleep apnea-related symptoms: snoring, sleepiness or morning headache
- To validate** the UPPP Prognostic Staging system (Friedman) for quality-of-life outcomes (measured with *Functional Outcomes of Sleep Questionnaire*) in UPPP patients
- To compare** outcomes of UPPP alone versus UPPP with tongue procedure(s) in Friedman Stage II & III patients

Reason for Study

UPPP, the most common surgical treatment for sleep apnea, significantly improves physiologic abnormalities in selected patients. Historically, however, UPPP appears undervalued as a treatment modality for sleep-apnea patients.

Recent studies support that UPPP helps in prevention of motor vehicle accidents, mortality and incidence of cardiovascular disease. Moreover, health-related quality of life, possibly the most important outcome to patients, barely has been evaluated in UPPP patients. A multi-site, community-based study can most accurately evaluate the treatment effectiveness of UPPP.

Procedure

The SLEEP study evaluates the effectiveness and disease-specific quality of life associated with surgical treatment of obstructive sleep apnea due to palatal and oropharyngeal obstruction. Since many patients with sleep apnea have multiple sites of obstruction, subjects will be stratified by concomitant procedures with UPPP.

Disease-specific quality of life will be measured with the *Functional Outcomes of Sleep Questionnaire (FOSQ)* at enrollment and at three months post-operatively. Other measures include: global assessment in improvement in sleep apnea; disease-specific quality of life at six months post-procedure; and post-procedure change in secondary problems present at enrollment (sleepiness, snoring, headache, *Nasal Obstruction and Septoplasty Effectiveness* scale).

The surgeon completes an eligibility form and an examination form within 10 days of surgery. The patient completes a baseline packet (demographics, medical history and habits, and outcome questionnaires) within 10 days of surgery. The Coordinating Center will have patients complete follow-up questionnaires at three and six months. Both questionnaires are short, simple and easy to complete.

BEST ENT Network

Physicians participating in the SLEEP study have the opportunity to become members of the BEST ENT Network coordinated by the National Center for the Promotion of Research in Otolaryngology (NCPRO). The BEST ENT Network works to expand and improve the evidence base for treatment options in otolaryngology. The BEST ENT Network was originally established by a generous grant from Schering-Plough Laboratories.

In fulfillment of the research mission of the American Academy of Otolaryngology—Head and Neck Surgery Foundation, NCPRO oversees clinical studies directly relevant to the day-to-day practices of Academy members, and to support the best outcomes of patients.

For More Information about the SLEEP Study

<http://www.entnet.org/research>

SLEEP



To Become A SLEEP Study Site please contact
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