**Uvulopalatopharyngolasty: does the specific surgical technique improve post-operative apnoea hypoxia index?**

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**Project Team**

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**Project Background:**

Uvulopalatopharyngoplasty (UPPP) is a procedure performed for obstructive sleep apnoea (OSA) with the aim to reduce snoring and obstructive events and therefore improve sleep quality and cardiopulmonary health. While continuous positive airway pressure (CPAP) is considered first-line treatment, there are issues with compliance, with many patients not tolerating CPAP due to discomfort or psychological and social impacts of being connected to a machine.

In April 2020, Mr Fogarty and Dr Wadhera published Mr Fogarty’s retrospective data on his cold steel technique of UPPP in the Australian Journal of Otolaryngology. Ninety-eight patients were identified as having had a UPPP with Mr Fogarty over a six-year period. This technique had a low incidence of post-operative complications and 66% of patients described the post operative level of pain as at most moderate and manageable. A high portion (93.6%) of patients described the procedure overall as “worth it” and there was an improvement in the patients’ quality of life based on daytime somnolence, sleep quality, snoring and sleep partner disturbance. However, less than half the patients (38) underwent pre-operative sleep study and only five underwent post-operative sleep studies. The question remains whether this technique improves a patient’s post-operative apnoea hypoxia index (AHI) on a formal sleep study. Moreover, the retrospective design of this study and questionnaire format may have resulted in a degree of reporting bias, as some patients were asked to comment on their subjective pre- and post-operative experiences that occurred up to six years previously.

**Study design:**

**Aims:**

This is a prospective cohort study with a primary aim to determine whether Mr Fogarty’s UPPP technique results in improved post-operative AHIs. Secondary aims include analysis of participants’ pre- and post-operative experience of sleep disordered breathing,

**Research project setting:**

This project will occur at Albury Wodonga Health and ENT Albury.

**Participants:**

This project will include adult patients who undergo UPPP with Mr Fogarty. Mr Fogarty performs about 15 -20 of these procedures per year and this study aims to recruit at least 20. Patients who are not competent to consent and paediatric patients will be excluded from the project.

**Participant recruitment strategies and timeframes:**

Patients recruited through the normal process of ENT consultant review in the Albury ENT rooms. There will be no requirement for screening. If UPPP is recommended for a patient for management of sleep-disordered breathing and they consent to undergo the surgery, involvement in the research project will be discussed with them by the ENT consultant surgeon or ENT registrar. The patients will be approached regarding their participation in person and a hard copy of the recruitment documentation will be provided to them. Non-English-speaking patients will be consented with the aid of a qualified medical interpreter. From the time of their recruitment, patients will likely have a couple of weeks to consider participation. We aim to recruit the patients over the next 6-12 months.

**Approaches to provision of information to participants and consent:**

Patients will be consented for participation during the normal process of elective surgical booking. The consent will be obtained by the ENT surgeon or ENT registrar who is consenting the patient for surgery. At the time of consent for the elective surgical procedure, the patient will be advised regarding the project and asked to give written consent to their participation. The patient’s consent to continue to as a participant in the study will be confirmed when they attend for their elective UPPP procedure.

**Research activities:**

The research participants will be asked to undergo both pre-operative and three months post-operative sleep studies through the Albury Wodonga Private Hospital. The out-of-pocket cost to participants is $80 per sleep study. Patients will also be asked to complete the Epworth Sleepiness Scale and Functional Outcomes of Sleep Questionnaire (FOSQ-10) both pre-operatively and at three months post-operatively. No other participant follow-up will be required beyond the usual surgical post-operative practice.

**Benefits**

This research project aims to benefit the participant by providing both subjective and objective measures of pre- and post-operative sleep disturbance. The study investigators predict that the surgery will provide demonstrable improvements in sleep quality but this has not yet been formally demonstrated in a research study. Patient participation will allow the investigators to determine the degree of improvement expected as a result of this surgical procedure. Assisting health research can help to benefit everyone by improving the delivery of care and increasing our understanding of human health and wellbeing, diseases, their treatments and side effects.

**Data collection / analysis**

The information gathered will include de-identified participant demographics, including age, sex, body mass index, airways disease, cardiovascular disease and smoking status; and pre- and post-operative questionnaire responses and AHI results.

*Data Management*

Data will be recorded in a spreadsheet format for later recall and analyses. Data will only be identified by code number for each patient with no link to their medical record. The code will be kept in a password-protected document on a password-protected computer. There will be no identifiable patient information in the spreadsheet. The spreadsheet will also be kept on a password-protected computer.

All data records will be retained for seven years prior to secure destruction.

*Data Analysis*

SPSS will be used to analyse data regarding any difference between pre-operative and post-operative AHI.

**Results, Outcomes and Future Plans**

The outcomes of this research is planned to be used for an article to be published in a peer reviewed journal. Participants will be advised regarding the article’s publication and will be able to obtain a copy.

**M6.2.1.2.8.1 – study registration with ANZCTR**