

The Day Surgery Sleep Survey (DURESS) Project – Study Protocol

Study Investigators

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## 1. Introduction

Sleep disturbance appears to be nearly universal post-operatively[1-7], and has been associated with increased rates of delirium, pain, cardiovascular events, and longer recovery times[7].

In spite of current research there remains uncertainty as to the degree and duration of sleep disruption post-operatively. In addition, the role, if any, that pharmacological agents commonly used in anaesthesia have on post-operative sleep disturbance is yet to be fully elucidated.

This study aims to explore the utility of a text message based survey to study perioperative sleep disruption in day surgery patients.

2. Background

Sleep is a key biological function that is highly conserved across animal evolution[8]. Sleep deprivation has been implicated in a number of adverse health effects including cardiovascular disease, diabetes, obesity, infertility, malignancy, dementia, and depression [9].

Surgery is associated with many risk factors associated with disordered sleep including the severity of surgical trauma, postoperative pain, opiate analgesia, and environmental factors [10]. Although there is debate over the exact influence that the type of anaesthesia plays, general anaesthesia agents have been implicated in significant perturbations on natural circadian rhythms [11].

Evidence based practice to limit the perioperative disruption to normal diurnal sleep patterns is limited. A 2016 meta-analysis concluded that pharmacotherapy was not shown to increase sleep quality or quantity in hospitalised patients [12]. Dexmedetomidine infusion for postoperative analgesia has been shown to improve sleep quality after hysterectomy [13] and in critically ill adults[10], although this has not been studied in day surgery.

Measurement of sleep quantity and quality can be divided in to objective and subjective. Objective methods include the gold standard of polysomnography and wrist actigraphy, with subjective methods including sleep diaries and sleep questionnaires. It may well be that these two categories are not looking at the same issue, “Objective measurements can better differentiate between sleep and wake , whereas subjective ones can determine the effects of the sleep disturbance on a patient’s life” [14]. Objective methods require relatively expensive equipment and can significantly limit the number of participants included in a sleep study.

Outpatient survey follow up has traditionally been done with phone calls or email based surveys, however the use of SMS text message based surveys has been shown to have high retention and response rates [15] and allows us to increase the number of participants in the study due to the automated nature of data collection. By demonstrating the response rate to postoperative sleep surveys and compare the findings on sleep disruption against previous standards we can demonstrate if a text messaged based system is viable for larger cohort sleep research.

If a text messaged based method for following up post-operative sleep disruptions can be shown to be effective, this will allow for larger scale research utilising this approach.

3. Aims of Study

To explore use of a text message-based survey system as a means of gathering large scale post-operative sleep data.

4. Objectives

1. Define the degree and duration of sleep disruption following day surgery compared to self-reported preoperative values.
2. Describe survey response rate and drop off with subsequent follow up survey requests.
3. Provide hypothesis generation for further studies to consider the role of pharmacological agents in perioperative sleep.

5. Hypothesis

5a. Primary Hypothesis

Sleep duration and quality after day surgery are negatively impacted when compared to preoperative values and return to normal within one week.

5b. Secondary Hypotheses

Participant responses to survey requests will be over 50% for the first survey and decrease to below 30% for the following two (based on personal correspondence with [CASTME.com.au](http://CASTME.com.au) from their response rates).

6. Study Design

A prospective cohort study.

7. Study Setting/ Location

This will be based over two locations for day surgery at Capital and Coast District Health Board, Wellington Regional Hospital, Wellington NZ, and Keneperu Hospital, Wellington NZ.

8. Study Population

Adults (age ≥18 years) undergoing non-cardiac day surgery (admitted, have surgery, and discharged on the same calendar day). Recruitment will occur over a 12 week period in which we estimate there will be 700 eligible patients based on previous case load over a similar time frame.

9. Eligibility Criteria

9a. Inclusion Criteria

Patients 18 years and older scheduled for elective day surgery under at Capital Coast District Health Board

9b. Exclusion Criteria

Any patients who are not discharged home on the same day as their surgery, if they had a known history of alcohol or drug abuse, diminished understanding or comprehension, poor English understanding, or they were aged less than 18 years old on the day of surgery.

10. Study Outcomes

10a. Primary Outcome

* Sleep quantity – self reported, measured in hours.
* Sleep quality – self reported, measured on an eleven-point numeric rating scale from 0 (worst) to 10 (best).

10b. Secondary Outcome(s)

Demographics – Age (years), sex (male, female, other), Ethnicity, American Society of Anaesthesiologists Physical Classification Status[16].

Surgery type by specialty.

Time of induction of anaesthesia.

Duration of Anaesthesia

Type of anaesthesia – general, general and regional, regional and sedation, regional alone, sedation alone, other

Specific medicines used intra-operatively (dose in mg) – benzodiazepines, dexmedetomidine, dexamethasone, opioids (morphine equivalents)

Use of sleeping tablets - type

Post-operative pain – visual analogue scale from 0 (no pain) to 10 (extreme pain)

11. Study Procedures

11a. Recruitment of participants

All patients >18 years old scheduled for elective surgery will be sent a participant information sheet, introducing and explaining the study with their preoperative pack. On the day of surgery anaesthetists, and researchers who have undergone an education session on the study, and consent issues related to this, will discuss this study with them, obtain informed consent for them to participate in the study, and specifically ask them to consider giving their consent for their cellphone number to be recorded for the text-based survey link.

If the patients agree, then their cellphone number, NHI and a sequential study ID number will be recorded on a paper study participant form. At the end of each day, these forms will be collated and entered into a REDCAP database, the cellphone number, email address, and study ID will be entered separately in to the castme web portal database.

A survey is sent to each participant, 24 hours post discharge, by text (or by email if there is no cellphone number) to their smartphone. They open either the text or email to be met with an introduction including the fact that by opening the next screen into the questionnaire, they will be consenting to the process. Participants will have to give consent (and therefore have the opportunity to withdraw from the study) with each survey.

Each participant has been identified within the castme database only by the unique study identification number, email address and smartphone number (if any).

Surveys will go out on days 1, 3, and 7 post operatively. Survey responses will be checked daily to ensure that there are no time sensitive medical issues that require action.

11b. Study procedure

The first survey link will be sent out to the patient via text messaging service on day 1 postoperatively. This will again include information about the study, and details of data storage and privacy. There will also be a link for more detail or how to contact us with any questions. If the patient chooses “I do not wish to be a part of this study”, or they do not respond after a further text message-based prompt, their data will be permanently deleted from castme, and the redcap database. If the patient has responded to the first survey request, they will receive two further surveys, one on day 3 post operatively, and one on day 7 postoperatively. Again, the consent process describe above will apply to each of the text based surveys sent.

We estimate that 70% of patients will initially give their consent for inclusion, and that the percentage of patients completing each subsequent survey will drop rapidly after the first survey.

Given the number of day case surgeries per week and the expected patient dropout rate, we expect it will take 12 weeks to attain 450 patients.

11c. Data Security

Initial paper forms with patient signatory consent will include a patient BRADMA label, with Full name, DOB, NHI, and address. These forms will be collected at the end of each day, and then stored in a locked file cabinet within the department of Anaesthesia.

The REDCAP database will be held within the CCDHB system, is only accessible from within CCDHB’s internal IT environment, requires username and password to login, and tracks all activity from users.

CASTME is based on a cloud computing service with all resources within Australia. The cellphone number and email address are removed (de-identified) before the survey result is recorded on the database web application, which is in an Australian Cloud Server. The REDCAP case number will remain to allow CASTME data to be matched with the correct REDCAP file. The cloud computing service used is fully iso27001 compliant and has passed independent penetration testing. If the patient does not fill out the first survey after prompts, then all of their data will be deleted.

At the conclusion of the study, the data will be transferred to a secure Wellington Hospital archiving site and stored for at least 10 years then destroyed as per New Zealand legislation (Health (Retention of Health Information) Regulations 1996).

11d. Measurement tools used

The preoperative patient collection form will have the patients BRADMA label attached for name, DOB, NHI, and admitting physician. The anaesthetist will complete data for type of surgery, type of anaesthesia, time of induction for anaesthesia.

If the first day postoperative survey is completed, then further intraoperative anaesthesia data for drug doses and timing of anaesthesia will be located in the safer sleep electronic anaesthesia record and entered into the REDCAP database. Information on ethnicity will be obtained from the patient’s electronic health record via the concerto medial application portal within CCDHB.

The CASTME survey tool will send out the postoperative questionnaire on day 1, 3, and 7, see the attached questionnaire.

11e. Safety considerations/Patient safety

We consider there are two main sources risks of harm or patient safety with a survey-based project such as this:

1. Survey research has been shown to potentially elicit both negative and positive emotional reactions (Labott).
2. A patient may try to follow up an important post-operative question or medical issue via the survey pathway rather than through the intended clinical pathway which could cause a delay in addressing this.

To ensure participant safety we will:

1. provide clear instructions that it is OK to not respond to a question or the survey and provide contact details for the study authors.
2. There will be a once-a-day check of survey responses to ensure that there are no time sensitive patient communications that need to be forwarded to the appropriate clinical services.
3. The appropriate contact details for postoperative questions for CCDHB will be provided on the survey and the patient information sheet.
4. Pausing after the first 50 patients to check that the pilot phase has provided usable responses to ensure that the study does not continue if not fit for purpose.
5. The study authors will meet once a week to discuss any issues arising from the study, or patient queries.
6. Any adverse or serious events will be immediately discussed with the Department of Anaesthesia research committee, and the study paused if appropriate.

12. Statistical Considerations and Data Analysis

As there is currently no known level of sleep disruption deemed to be clinically significant no formal hypothesis test will be undertaken. Rather, differences in mean (or median if data is non-parametric) sleep quantity and quality will be assessed independently between pre-operative values and values obtained on post-operative days 1, 3, and 7 with a point estimate and attendant 95% confidence interval. An interval that crosses the null value (a difference of 0 hours in the case of sleep quantity, and a difference of 0cm in the case of sleep quality) would be deemed insufficient evidence to conclude there is a difference in that outcome on that post-operative night compared to pre-operative values.

Two separate multivariate linear models will be used to investigate the association between the other variables collected and sleep quality and quantity.

No correction will be made for multiple testing as the aim of this study is hypothesis generation; conclusions should therefore be treated as such.

13. Ethical Considerations

This study will be conducted in full conformance with the principles of the “Declaration of Helsinki”, good clinical practice, and within the laws and regulations of New Zealand.

The potential benefits of this study are to enhance our current understanding of postoperative sleep disruption and provide hypothesis generation for further page scale focused research on individual aspects of care that can promote less sleep disruption, and hence less morbidity after surgery. The patients risk clinically are low, since there will be no change to their usual clinical care. Survey research can elicit negative emotions, and we have demonstrated plans in place for this above. The main risk to patients is privacy of their electronic data. All paper records will be kept in a locked cupboard in the department of Anaesthesia, Wellington Hospital. These will be kept in paper format for 5 years after the end of the study, and then destroyed. The REDCAP database is password protected and only accessible from within the CCDHB IT system. The CASTME database is external to CCDHB and has two factor authentication systems.

The informed consent process has been detailed above. Some barriers to informed consent could be learning difficulties, vision problems, or English language reading and comprehension. We do not have patient information sheets in multiple languages available, however if any patients have queries and are limited by English language communication, we are able to access the health interpreter service through CCDHB to assist with this.

Issues related to survey responses include socioeconomic factors precluding ownership of a smartphone, or the data allocation to utilise it. These factors can be unevenly spread in our society potentially leading to uneven representation in responses from participants of differing ethnicities, income groups, and age groups. As part of our analysis, we will compare the demographics of patients invited to the survey and sub analyse response rates to show these differences in our results. The ability for CASTME to follow up with an email survey link if no text-based response can provide an option for those with no smart phone or mobile data, but the ability to access email.

14. Outcomes and Significance

Sleep is vital to our health and wellbeing and can impact our ability to get better after surgery. The current literature is sparse, and tools such as actigraphy are cost prohibitive. By demonstrating if a text-based survey for day surgery patients is effective, we will be able to provide a basis for further large-scale research into a potentially important pillar of post-operative health.

15. References

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## DURESS Study – Initial patient data form

Thank you for assisting with this study. Any questions, please contact Dan Ramsay or Phil Quinn.

Patient label

 **ASA**

* + I
	+ II
	+ III
	+ IV
	+ V

**Time of induction of anaesthesia** \_\_\_:\_\_\_

**Time of exit from theatre** \_\_\_:\_\_\_

**Surgery type**

* Dental
* ENT
* General
* Gynaecology
* Maxillofacial
* Neurosurgery
* Ophthalmology
* Obstetrics
* Orthopaedics
* Plastics
* Radiology
* Urology
* Vascular
* Other – please state\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Type of anaesthesia:

* General anaesthesia
	+ Volatile
	+ TIVA
	+ Other – please state
* General + regional anaesthesia
	+ Volatile
	+ TIVA
	+ Other – please state
* Regional anaesthesia + sedation
* Regional alone
* Sedation alone

Was there a premed other than paracetamol or an NSAID?

* No
* Yes
	+ Please detail drug/s and dosage: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_