STUDY TITLE:

INCIDENCE OF AND FACTORS ASSOCIATED WITH POST-OPERATIVE NAUSEA AND VOMITING FOLLOWING SURGERY UNDER REGIONAL ANAESTHESIA

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1.1 STUDY DESIGN

This was a prospective cohort study.

1.2 STUDY SETTING

This was a single center, hospital based study done in Mulago National Referral Hospital. Mulago National Referral Hospital is the Makerere University teaching hospital and is located in Kampala. It has a 1500 bed capacity but can admit up to 2500 patients.

This study was carried out in various theatres of Mulago hospital from August 2018 to January 2019. The theatres that were used for this study were: the main operating theatre, obstetrics and gynecology theatres, the orthopedics and ophthalmology theatres. These were a total of eight operating tables with an average of fifteen surgeries daily.

1.3 STUDY POPULATION

The target population was all patients 18 years of age and above scheduled for an elective or emergency surgical procedure under regional anaesthesia at Mulago hospital. The accessible population included all patients attending Mulago hospital for elective and emergency surgery under regional anaesthesia during the study period from August 2018 to January 2019.

1.4 ELIGIBILITY CRITERIA

1.4.1 INCLUSION CRITERIA

Patients having emergency or elective surgery under regional anaesthesia.
Patients aged 18 years and above.
ASA class 1, 2, 3 and 4 patients
Patients who consented to being a part of the study.

1.4.2 EXCLUSION CRITERIA

Patients who were switched to general anaesthesia after planned regional anaesthesia.

Patients with nausea and vomiting from pre-existing co-morbidities.

1.5 SAMPLE SIZE CALCULATION

Objective 1

Assuming an incidence of PONV in regional anaesthesia of 31.4%(Quinn et al., 1994) with an absolute error of 0.05 and 95% CI

Using Kish Leslie formula:

$$N=\frac{Z^2 P (1-P)}{D^2}$$

Where N=sample size required to determine incidence

Z is the value corresponding to 95% confidence interval=1.96

P is the prevalence of PONV among patients undergoing surgery under regional anaesthesia=0.314 from previous studies

D is the absolute error=0.05

$$N=\frac{1.96 \times 1.96 \times 0.314 (1- 0.314)}{0.05 \times 0.05}$$

N =331patients

Adjusting for loss to follow up of 10%

N =n (100+10)/100

=331(100+10)/100

=364 patients

Objective 2

From the comparison of two proportions formula:

$$N = \frac{\left(Z\alpha\sqrt{\left(\frac{1}{q1}+\frac{1}{q2}\right)P(1-P)} + Z\beta\sqrt{P1(1-P1)\frac{1}{q1}+P2(1-P2)\frac{1}{q2}}\right)^2}{(P1-P2)^2}$$

Using the factor of gender for PONV in regional anaesthesia according to a study by AC Quinn et al 1994

q1 is proportion of males in study =336/606=0.554

q2 is proportion of females in study =270/606=0.446

p1 is proportion of males with PONV =22/336 =0.065

p2 is proportion of females with PONV =47/270 =0.174

P=p1q1+p2q2= (0.065x0.554+0.174x0.446) =0.03601+0.0776=0.1136~0.114

Zα is standard normal corresponding to level of significance. Using a level of significance of 5%, Zα= 1.96

Zβ corresponds to power of the study. For a power of 80% Zβ = 0.841

N=272patients

Therefore, choosing the larger sample size from the calculation for sample size for the first objective; the sample size used was 364 participants

1.6 SAMPLING METHOD

Consecutive sampling was used until the sample size was attained.

1.7 SAMPLING PROCEDURE

Patients 18 years or older that had been admitted for either elective or emergency surgery under regional anaesthesia were selected while in the pre-operative waiting area. Screening for eligibility was done by the principal investigator or by the research assistants. Patients that met the eligibility criteria were then consented and enrolled into the study. Patient data was gathered using a pretested questionnaire that included age, sex, medical history, anaesthetic technique used, duration of surgery, intraoperative medication and any nausea or vomiting within 24hours of surgery. Patients were followed up for up to 24 hours post-operatively.

1.8 DATA MANAGEMENT

1.8.1 DATA COLLECTION

A standardised questionnaire was completed by the study research assistants or the principal investigator during the immediate pre-operative period to assess pre-operative risk of post-operative nausea and vomiting. The information collected included patient demographics, past medical history, information on fasting and co-morbidities. A second questionnaire was used to assess the perioperative conduct of anaesthesia and any events occurring within this period. It contained the follow up information as well.

Patients were followed up once at 24 hours to assess for post-operative nausea and vomiting.

1.8.2 INDEPENDENT VARIABLES:

Socio demographic data such as age and sex, the diagnosis and type of procedure, ASA classification, history of PONV or motion sickness, non-smokers, peri-operative opioid use, period of pre-operative fasting, PONV prophylaxis use, duration of anaesthesia and surgery were studied.

1.8.3 DEPENDENT VARIABLE:

Post-operative nausea and vomiting measured by any retching, nausea or vomiting within 24 hours following surgery under regional anaesthesia.

1.8.4 DATA ANALYSIS AND SAFETY

Completeness and accuracy of data was checked daily and organised by the principal investigator before storage. Data was double entered into the computer using EPI data version 3.1, and then subsequently exported to STATA version 14.0 for analysis.

Analysis was done using STATA with the help of a statistician. Both raw data and the analysed form were kept both electronically and hardcopy for further reference.

All questionnaires were stored in a secure, waterproof place to enable confidentiality and were only available to the principal investigator.

Participant characteristics were expressed as categorical and/or continuous variables.

Continuous variables were expressed as means and standard deviations while categorical data was expressed as frequencies with their respective proportions. Data presentation is in tabular and graphic forms.

Cumulative incidence was assessed as the proportion of study participants who developed PONV within 24 hours of follow up divided by the total number of study participants enrolled into the study with complete follow up.

At the bivariate level, each variable was compared with the outcome variable using cross tabulation and the logistic analysis. Variables that had p-value less than 0.200 at bivariate analysis were considered for multivariate analysis using logistic regression and variables were considered significant if the p-value <0.05.

1.8.5 QUALITY CONTROL AND ASSURANCE

Pre-testing of the questionnaires was done on non-study participants and changes made to the questions where necessary before final data collection.

Translation of the consent form into Luganda, the main local language used in Mulago was done prior to the start of data collection.

Research assistants were trained on how to obtain informed consent, patient approach and proper data collection before data collection commenced.

All questionnaires were safely stored to enable revisiting them when necessary.

1.9 ETHICAL CONSIDERATIONS

Ethical approval was sought from the School of Medicine Research and Ethics Committee (SOMREC).

Permission was sought from the Mulago Hospital Ethics committee.

Informed consent was sought from the study participants.

Confidentiality was observed throughout the study.

DATA COLLECTION TOOL

INCIDENCE OF AND FACTORS ASSOCIATED WITH POST-OPERATIVE NAUSEA AND VOMITING AMONG PATIENTS UNDERGOING REGIONAL ANAESTHESIA

QUESTIONNARE 1 (to be completed by the principal investigator or research assistants)

Study Number: .....

Patient's name: .....

Patient's telephone number(s) 1..... 2.....

Pre-operative assessment

1. **Case details (state)**

   1.1 Diagnosis…… 1.2 Procedure……..

2. Urgency of Surgery (Tick one)

2.1 Elective ☐

2.2 Emergency ☐

3. Patient details (preoperative assessment as recorded)

3.1 Age (years) 18-30 ☐ 31-50 ☐ >50 ☐

3.2 Sex M ☐ F ☐

3.3 Weight.....kg.

3.4 ASA classification 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

3.5 Pulse..... /min. 3.6 BP.....

4. Patient experience

4.1 Have you had nausea or vomiting before?

1=Yes ☐ 2= No ☐

4.2 How would you describe the experience?

1=Very unfavorable ☐ 2=Unfavorable ☐ 3=Neutral ☐

5 Risk factors for post-operative nausea and vomiting

5.1 Does the patient have any of the following? (Tick appropriately)

(Multiple choices apply)	1=Yes	2= No
Female	☐	☐
History of PONV	☐	☐
History of motion sickness	☐	☐
Alcohol use	☐	☐
Smoker	☐	☐

5.2 Time since the last feed (tick appropriately)

2hrs ☐ 4hrs ☐ 6hrs ☐ 8hrs ☐ >8hrs ☐

5.3 Type of feeds (tick) ……

Solids ☐ semi-solids ☐ liquids ☐

QUESTIONNAIRE 2

Study Number: .....

Patient's name: .....

1. **Anaesthesia provider (Tick)**

   1.1 AO student trainee ☐ 1.2 AO ☐ 1.3 SHO ☐ 1.4Anaesthesiologist ☐

2. **Length of the operation**

   2.1 Time surgery i) started……. ii) ended (state in 24hour clock) …….

   2.2 Duration of anaesthesia

   30 min ☐ 30-60min ☐ 60-120min ☐ >120min ☐

   2.3 Duration of surgery

   30 min ☐ 30-60min ☐ 60-120min ☐ >120min ☐

3. **Conduct of anaesthesia and surgery**

   3.1.Type of Surgery

   Emergency ☐

   Elective ☐

   3.2.Anaesthetic technique (state) …….

   Sedation used 1=Yes ☐ 2=No ☐

3.3. Number of attempts at the block(tick) 1 ☐ 2 ☐ >2 ☐

3.4.Drugs used during anaesthesia(tick)

	1=Yes	2=No
Opioids	☐	☐
If yes, state which opioid …….		
Anti-emetics	☐	☐
If yes, state which anti-emetic …….		
Sedatives	☐	☐
If yes, state which sedative …….		

3.5.Did any of the following happen during surgery? (Tick appropriately)

	1=Yes	2=No
Retching	☐	☐
Nausea	☐	☐
Vomiting	☐	☐

3.6.Lowest BP recorded(tick)

SBP <110	☐	<90	☐	<50	☐
DBP <90	☐	<70	☐	<50	☐

4. Recovery room

5.1 Did any of the following happen during recovery? (Tick appropriately)

	1=Yes	2=No
Retching	☐	☐
Nausea	☐	☐
Vomiting	☐	☐

5. At 24 hours (tick)

5.1 Nausea or vomiting 1= Yes ☐ 2=No ☐

5.2 If yes, time to occurrence of PONV from time of surgery……hours……min

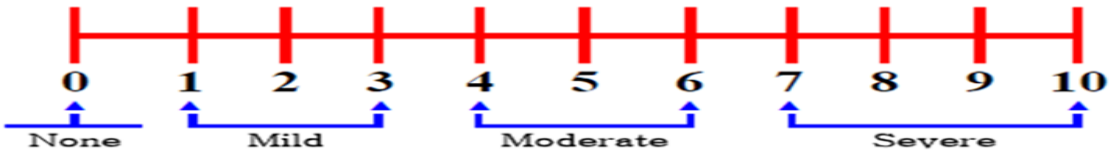
5.3 Post-operative opioids received 1=Yes ☐ 2=No ☐

If yes, state which opioid …….

6. Pain assessment

6.1Peri-operative pain 1=Yes ☐ 2=No ☐

6.2 Numerical Pain Rating Score: ..... (Out of ten)



Rating	Pain Level
0	No Pain
1 – 3	Mild Pain (nagging, annoying, interfering little with ADLs)
4 – 6	Moderate Pain (interferes significantly with ADLs)
7 – 10	Severe Pain (disabling; unable to perform ADLs)

RISK FACTORS FOR NAUSEA AND VOMITING SCORING SYSTEM (aPFEL)

Risk Factors	**Points**
Post-operative Opioids	1
Non Smoker	1
Female Gender	1
History of PONV/Motion Sickness	1
Risk score = sum	**0 ... 4**