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Does propofol prevent morphine-induced nausea, vomiting and itching in women who have had a Caesarean section?

Submission date
01/04/2019

Recruitment status
No longer recruiting

Registration date
03/04/2019

Overall study status
Completed

Last Edited
16/09/2019

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background: Postoperative Nausea and Vomiting (PONV) is a dreadful and uncomfortable experience that significantly detracts patients' quality of life after surgery. It increases perioperative costs, morbidity, prolongs hospital stay and increase re-admissions rates. Despite the existence of multiple risk stratification tools and treatment guidelines, clinicians are yet to establish a uniform fashion with both pharmacologic and non-pharmacologic strategies which alleviate the occurrence of PONV. This study aimed to examine the antiemetic effect of a single sub-hypnotic dose of propofol as prophylaxis for PONV.

Method: In this prospective comparative study, 360 parturient presented for elective cesarean section at the Obstetric unit of Tamale Teaching Hospital were recruited. Each recruited parturient was randomly assigned to one of three groups; Propofol group (n = 120) represented those who received propofol (0.5 mg/kg), Metoclopramide group (n = 120) represented those who received metoclopramide (10 mg) and, Control group (n = 120) represented those who received 0.9% saline. Spinal anesthesia with 0.5 % hyperbaric bupivacaine (7.5 mg - 10 mg) and intrathecal morphine (0.2 mg) was employed for the anesthesia.

Results: The data indicate that 108 (93.91 %) parturient from the control group, 10 (8.69 %) from the propofol group and 8 (6.96 %) from the metoclopramide group experienced some incidence of PONV. Parturient who received antiemetic agents were 105 (97.22 %), 1 (10.00 %) and 3 (37.50%) from the control, propofol and metoclopramide groups respectively. No incidence of pruritus was experienced among 17 (14.78 %) parturient from the control group, 112 (97.39 %) from the propofol group, and 15 (13.04 %) from the metoclopramide group, whereas 98 (85.22 %), 3 (2.61 %) and 100 (86.96 %) parturient from the control, propofol, metoclopramide groups respectively experienced some levels of pruritus.

Conclusion: This study findings suggest that a sub-hypnotic dose of propofol is equally effective as metoclopramide in the prevention of PONV in parturient undergoing cesarean section under spinal anesthesia with intrathecal morphine. The sub-hypnotic dose of propofol also significantly reduced the incidence of postoperative pruritus following intrathecal morphine use.

Keywords: Antiemetic, prophylaxis, Propofol, Metoclopramide, Postoperative Nausea and Vomiting, Pruritus, Parturient, Cesarean Section.

Background and study aims
Postoperative nausea (feeling sick) and vomiting (PONV) is caused by some drugs commonly used in surgery, including general anesthetics used to make a patient unconscious and analgesic (pain-blocking) drugs. It is uncomfortable experience that reduces patients' quality of life in the recovery period and can put people off having surgery. PONV also increases hospital costs, illness, hospital stay times and re-admission rates. There is not yet agreement of the best way to prevent PONV. This study aims to investigate whether giving a low dose of propofol (a drug that reduces consciousness and memory for a short time) after surgery can prevent PONV.

Who can participate?
Women who are having a planned Caesarean section.

What does the study involve?
The participants will be randomly allocated into one of three groups. They will all have the Caesarean section procedure as usual, which includes anesthetic drugs being injected into the spinal cord so that they cannot feel the pain and discomfort of the Caesarean section. After the baby has been born and the surgical procedure is finished, the participants will receive an injection of saline (salt water containing no drugs), metoclopramide (a drug known to prevent nausea and vomiting) or propofol, depending on which group they were allocated to. The participants will then be monitored in the hospital for 24 hours. If they experience pain, nausea and vomiting or itching, they can request medicines to help with these symptoms.

What are the possible benefits and risks of participating?
The drugs used in the study are generally safe and doctors are experienced in using them, however participants might experience side effects. Patients who receive saline might experience more nausea and vomiting that those in the other two groups, but they will receive medicines to treat these symptoms.

Where is the study run from?
The University for Development Studies (Ghana)

When is the study starting and how long is it expected to run for?

Who is funding the study?
The University for Development Studies (Ghana)

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
TTHERC21/04/16/08

Study information

Scientific Title
A sub-hypnotic dose of propofol as antiemetic prophylaxis attenuates intrathecal morphine-induced postoperative nausea and vomiting, and pruritus in cesarean section

Study objectives

This study was designed to test the hypothesis that propofol use as antiemetic prophylaxis prevents intrathecal morphine-induced postoperative nausea and vomiting, as well as pruritus in cesarean section.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/05/2016, Tamale Teaching Hospital Ethical Review Committee (Tamale Teaching Hospital PO Box 16, Tamale, Ghana; +233 03720 22545/22483), ref: TTHERC21/04/16/08

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Morphine-induced postoperative nausea and vomiting in women who have had a Caesarean section

Interventions
360 women with no history of obstetric complications or co-morbidity who report at the obstetric unit of the Tamale Teaching Hospital for elective Caesarean section will be recruited for this study, after obtaining written informed consent. Each recruited participant will then be randomly assigned to one of three groups using a computer-generated random number table. The group allocation will be concealed in a sealed opaque envelope which will be opened just before the administration of the drugs. The propofol group (n = 120) represents those who will receive intravenous propofol (0.5 mg/kg), the metoclopramide group (n = 120) represents those who will receive intravenous metoclopramide (10 mg) and the control group (n = 120) represents those who will receive intravenous saline (0.9 %) as negative control.

All women were prospectively assessed and classified according to the America Society of Anesthesiologist (ASA) physical status classification. Basic intraoperative monitoring (ECG, peripheral capillary oxygen saturation [SpO2], temperature and non-invasive blood pressure) were applied and the baseline vital signs checked and recorded. All participants had no history of nausea or vomiting. Before surgery, the participant was advised not to eat any solid food for at least 6-8 h. An independent anesthesiologist specialized in obstetric anesthesia was assigned to perform the spinal anesthesia and monitor the participant until discharged from the hospital.

In the sitting position, the skin and interspinous ligaments were infiltrated with 2 ml of preservative-free 2 % lidocaine using a 21G hypodermic needle. Lumbar puncture was then performed aseptically using a 26G pencil point spinal needle by the midline approach at the lumbar region (L2-L3 or L3-L4 interspace). Successful insertion of the spinal needle into the subarachnoid space was confirmed by the presence of the free flow of cerebrospinal fluid. The subarachnoid block was then established with 10 mg preservative-free hyperbaric bupivacaine, and 0.2 mg morphine. The participant was then asked to return to the supine position with her head supported on a pillow and slightly tilted up to avoid any further spread of the spinal agent toward the head. A left lateral tilt for uterine displacement was employed to prevent aortocaval compression. The vital signs (pulse rate, blood pressure, oxygen saturation, and respiratory rate) of the participant was monitored and recorded every 5 min for the first 30 min and then every 15 min. An ice cube was used to confirm adequate sensory block up to T6 level. Supplemental oxygen was given at 3 l/min through nasal prongs. Intraoperative hypotension was treated with 5-20 mg of intravenous ephedrine. Any estimated fluid deficit or blood lost was replaced accordingly. After the delivery of the baby, 5-10 U of intravenous oxytocin was given to aid uterine contraction. A different independent anesthesiologist, who was blinded to drugs application, was then asked to inject the participant with saline (0.9 %), metoclopramide (10 mg) or propofol (0.5 mg/kg) 10-15 minutes before the end of surgery. Participants were monitored hourly for the first 4 h and then every 4 h up to 24 h. Kytril (granisetron) 1 mg was administered if vomiting ensued or on request. If rescue analgesia was required, the participant received a 100 mg diclofenac suppository or an injection of 100 mg tramadol or both. Naloxone hydrochloride (2 µg/kg) or cetirizine (10 mg) was administered upon request to treat pruritus.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Morphine, bupivacaine, propofol, metoclopramide

Primary outcome measure
1. Episodes of postoperative nausea and vomiting (PONV) assessed using using a 3-point ordinal scale (0 = none, 1 = nausea, 2 = vomiting) recorded hourly for the first 4 h and then every 4 h for the next 24 h. The incidence of PONV was calculated and categorized as early (0-4 h) or delayed (5-24 h).
2. Rescue antiemetic use up to 24 h after metoclopramide, propofol or saline administration

Secondary outcome measures
1. Episodes of pruritus assessed using a four-point categorical scale (0 = no pruritus, 1 = mild pruritus, 2 = moderate pruritus, 3 = severe pruritus) hourly for the first 4 hours and then 4 hourly for the next 48 hours after surgery
2. Pain intensity assessed using a 100-mm visual analog scale VAS (Mc Cormack et al, 1988), where 0 mm = no pain, and 100 mm = intolerable pain, immediately after surgery
3. Overall perioperative satisfaction evaluated during an interview, where 4 = excellent, 3 = good, 2 = satisfactory, 1 = poor, on the day of hospital discharge

Overall study start date
28/02/2016

Completion date
24/05/2017

Eligibility

Key inclusion criteria
Women undergoing elective Caesarean section

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
400

Total final enrolment
345

Key exclusion criteria
1. Women undergoing emergency Caesarean section
2. Women who have refused to give consent to the study
3. Any co-morbidity

Date of first enrolment
26/05/2016

Date of final enrolment
23/05/2017

Locations

Countries of recruitment
Ghana

Study participating centre
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Funder type
University/education

Funder Name
University for Development Studies

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/07/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/09/2019	16/09/2019	Yes	No