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Comparison of using two doses of ephedrine to reduce low blood pressure with propofol for general anaesthesia

Submission date
29/08/2021

Recruitment status
No longer recruiting

Registration date
28/09/2021

Overall study status
Completed

Last Edited
27/09/2021

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
During the procedure of giving General Anaesthesia to a patient before surgery, there are multiple drugs used so that the patient may be unconscious and pain-free. One of the drugs used is Inj. Propofol, which is used to induce sleep in the patient. This drug is known to cause a fall in blood pressure levels.
Ephedrine is a drug that has been shown to be beneficial and will raise blood pressure levels to counteract the effects of propofol during general anaesthesia.
Ephedrine during induction of general anesthesia, also hastens the onset of action of muscle relaxant and improves the ease of intubating a patient with an endotracheal tube.
Aims
1. To compare the efficacy of two doses of ephedrine to reduce the fall in blood pressure caused by propofol in patients receiving general anaesthesia.
2. To compare the intubating conditions with the use of two doses of ephedrine with propofol in general anaesthesia.

Who can participate?
Adults between the age of 20-60 years undergoing elective surgery under general anaesthesia

What does the study involve?
Patients were allocated into each group based on a randomised lot system.
Group S1 included 29 patients who received normal saline intravenously as a dummy drug followed by propofol.
Group E1 had 29 patients who were given ephedrine 100mcg/kg intravenously followed by propofol.
Group E2 included 29 patients who received ephedrine 150 mcg/kg followed by propofol.
Heart rate, Blood pressure and Mean arterial pressure was measured before induction and 2min after induction. Following intubation, the parameters were recorded at 1min, 3min, 5min, 10min, 15min and 30 min.

What are the possible benefits and risks of participating?
The possible benefits included improved hemodynamic stability throughout the surgical procedure. There was less hypotension with our anaesthetic drug propofol when it was used in combination with ephedrine.
The possible risks included persistent low blood pressuredespite the use of ephedrine. Also, some degree of increased heart rate with the use of ephedrine is known to occur.

Where is the study run from?
St. John's Medical College Hospital (India)

When is the study starting and how long is it expected to run for?
August 2015 to August 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A comparison of two prophylactic doses of ephedrine to attenuate the hemodynamic responses in adults receiving propofol in general anaesthesia.

Study objectives
PRIMARY OBJECTIVE:
To compare the efficacy of two prophylactic doses of ephedrine to attenuate the hypotensive effects of propofol in patients receiving general anaesthesia.
SECONDARY OBJECTIVE:
To compare the intubating conditions with the use of two prophylactic doses of ephedrine with propofol in general anaesthesia.
NEED FOR STUDY:
The use of propofol has several potential advantages like, fast onset of action, potent attenuation of pharyngeal, laryngeal and tracheal reflexes and adequate depth of anaesthesia for intubation. However, a major disadvantage of propofol induction is the considerable fall in systemic arterial blood pressure. Several underlying mechanisms, like the fall in systemic vascular resistance and in cardiac output caused by a combination of venous and arterial vasodilation, impaired baroreflex mechanisms, and depression of myocardial contractibility have been suggested.
Ephedrine is a vasopressor used during anaesthesia to counteract the decrease in arterial blood pressure and heart rate after spinal or epidural anaesthesia. It is an α- vasoconstrictor and β-cardiostimulant. Its action is short lived, so has a similar duration of action like propofol. There have been various methods tried to combat these hemodynamic changes. In this study ephedrine will be used to study its effects on hemodynamics when administered with propofol. It has also been stated in previous studies that the use of ephedrine during induction of general anesthesia has been described to accelerate the onset of action of muscle relaxant and improve intubating conditions(11,12). This study will also evaluate the intubating conditions with prophylactic ephedrine with atracurium use.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 05/12/2015, Institutional Ethics Committee (St. John's National Academy of Health Sciences, Ground Floor, St. John's Medical College, Bangalore – 560 034, India; +91 80 – 49466346 / 48; sjmc.ierb@stjohns.in), ref: 335/2015

Study design
Prospective comparative interventional non-randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Attenuation of hemodynamic responses of propofol during induction of general anesthesia in adult patients.

Interventions
Patients were allocated into each group based on a randomised lot system. Group S1 included 29 patients who received normal saline intravenously as placebo just before induction, followed by propofol. Group E1 had 29 patients who were given ephedrine 100mcg/kg intravenously just before induction followed by propofol. Group E2 included 29 patients who received ephedrine 150 mcg/kg intravenously just before
induction followed by propofol.

After obtaining written informed consent for the study, adults of ASA PS I & II posted for surgery under general anesthesia were enrolled for the study.
A pre-induction recording of heart rate, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), and Mean Arterial Pressure (MAP) were taken for all patients. All
patients received 10 µg/kg glycopyrrolate, 0.15 mg/kg ondansetron and 0.05mg/kg of midazolam. Pre oxygenation was done. After pre-oxygenation, 2 mcg/kg of fentanyl was given intravenously. Following this, 1min later, group S1 patients received 2ml of normal saline intravenously, Group E1 received 100mcg/kg of ephedrine intravenously and Group E2 received 150 mcg/kg of ephedrine intravenously.
Anaesthesia was induced after the test drug injection using propofol 2mg/kg given IV over 30seconds until loss of consciousness and verbal responses. Endo tracheal intubation was facilitated with muscle relaxation with 0.5mg/kg of atracurium. Endo tracheal intubation was facilitated with muscle relaxation with 0.5mg/kg of atracurium64.

Heart rate, SBP, DBP, and MAP were measured before induction and 2min after induction. Following intubation, the parameters were recorded at 1min, 3min, 5min, 10min, 15min, and 30 min.
Rescue ephedrine IV was given to patients belonging to either group if the systolic blood pressure fell below 80mmHg or a fall of more than 20% decrease in SBP from
baseline was noted.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
ephedrine

Primary outcome(s)
Heart rate, systolic and diastolic blood pressure, and mean arterial pressure were measured using continuous monitoring equipment before induction and 2min after induction. Following intubation, the parameters were recorded at 1min, 3min, 5min, 10min, 15min and 30 min.

Key secondary outcome(s))
Intubating conditions evaluated according to the good clinical practice in pharmacodynamic studies of neuromuscular blocking agents ii: the Stockholm revision guidelines at the time of intubation

Completion date
01/08/2017

Eligibility

Key inclusion criteria
1. Adults between the ages of 20-59 years undergoing elective surgery under general anaesthesia.
2. ASA I and II patients.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
87

Key exclusion criteria
1. Patient refusal.
2. Patients allergic to study medication
3. Uncontrolled cardiovascular, respiratory, renal, or hepatic disease.
4. Morbid obesity.
5. Pregnant patients

Date of first enrolment
01/01/2016

Date of final enrolment
01/08/2017

Locations

Countries of recruitment
India

Study participating centre
St. John's Medical College Hospital
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Sponsor information

Organisation
St.John's National Academy of Health Sciences

ROR
https://ror.org/03qvjzj64

Funder(s)

Funder type
Other

Funder Name
investigator inititated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			27/09/2021	No	Yes