INPLASY

Comparing Efficacy of Pharmacological Treatment of Post Central Neural-Axial Anaesthesia Shivering: A Systemic Review and Network Meta-analysis with Incorporation of Dose Effect

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ADMINISTRATIVE INFORMATION

Support - Nil.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202420088

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 February 2024 and was last updated on 21 February 2024.

INTRODUCTION

Review question / Objective Objective: 1. To find out efficacy drug as treatment for post central neural axial anaesthesia
a. Effective rate
b. Time to stop shivering
c. Recurrent rate of shivering
d. Effective rescue medication for shivering
2. To identify drug with the least side effect profile after treatment of shivering
3. To investigate the prevalence of adverse effect in pharmacological treatment of shivering. Mainly:
a. Hypotension
b. Bradycardia
c. Sedation
d. Nausea
e. Vomiting.

Rationale Central Neural Axial Blocks is a common mode of anaesthesia which mainly for lower limbs surgery, lower abdominal surgeries and caesarean sections. Shivering is a common observed phenomenal where as high as 85% is reported.
Shivering is defined as involuntary, spontaneous, oscillatory muscular activity that augments metabolic heat production. It can be a respond to hypothermia but can occur too despite patient is normothermia. It is not unexpected to be ranked as 6th most important problem of current anaesthesiology practice (Bhukal I , 2011).
Proposed mechanism of shivering are greater heat lost in regions with CNA blockade due to vasodilatation and impaired mechanism of shivering due to motor blockade in CNA.
Consequences include :
1. Patient : discomfort, increases in oxygen consumption, catecholamine secretion, carbon dioxide production, metabolic rate increase by 400% with increase intraocular pressure (IOP), Intracranial pressure (ICP), and lactic acid production.
2. Surgeon : affecting operating process due to patient shivering

3. Anaesthetist : affecting monitoring such as spo2 monitoring and blood pressure monitoring (DINAMAP) , ECG
Multiple RCT has been done to find out drug that is effective treating post CNA shivering, this research project aim to find out the drug with best efficacy and most desirable side effect profile
Hences the purpose of the study is:
1. To find out efficacy drug as treatment for post central neural axial anaesthesia
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Condition being studied Post central neural axial blockade (spinal anaesthesia , epidural anaesthesia ,combine spinal epidural anesthesia) shivering
Population : patient who under go lower abdominal surgery, orthopedic lower limb surgery, caesarean section.

METHODS

Search strategy Following the PRISM statement, PubMed, CINAHL, Cochrane, EMBASE, Google scholar and other grey literature databases will be searched for eligible studies. Two individuals independently assessed trial eligibility, abstracted data, and assessed the risk of bias. Bayesian network meta-analyses will be performed
Inclusion criteria
1. Randomized control trials investigating pharmacological treatment for post central neural axial anaesthesia shivering.
2. ASA1, ASA 2 and ASA 3 cases for lower limb surgeries , lower abdominal surgeries including caesarean section.
3. Trials were eligible for our network meta-analysis if they were reported to be randomized parallel group trials (i.e., crossover trials were not eligible)
4. RCT including language other than English. Provided study is translated officially by the journal they published.
Exclusion criteria
1. Studies other than randomized control trial.
2. Studies that do not report treatment dosing information cannot be included
3. Incomplete Studies – On going recruitment , paper yet to publish
4. Raw paper not available despite best effort – contacted author and no reply.
5. Study criteria
a. General Anaesthesia case
b. Prevention of shivering instead of treatment
c. Intrathecal administration of drug.

Participant or population Patient who undergo surgery such as caesarean section , orthopedic lower limb surgery , non obsteric lower abdominal surgery , ASA 1 ,2 ,3 . Patient who given central neural axial blockade.

Intervention Pharmacological treament for post central neural axial blockade shivering.

Comparator Comparison between each of the pharmacological treaement.

Study designs to be included Only randomized control trial regarding treatment given for shivering developed post central neural axial blockade.

Eligibility criteria Inclusion criteria1. Randomized control trials investigating pharmacological treatment for post central neural axial anaesthesia shivering.2. ASA1, ASA 2 and ASA 3 cases for lower limb surgeries , lower abdominal surgeries including caesarean section.3. Trials were eligible for our network meta-analysis if they were reported to be randomized parallel group trials (i.e., crossover trials were not eligible)4. RCT including language other than English. Provided study is translated officially by the journal they published.Exclusion criteria1. Studies other than randomized control trial.2. Studies that do not report treatment dosing information cannot be included3. Incomplete Studies – On going recruitment , paper yet to publish4. Raw paper not available despite best effort – contacted author and no reply.5. Study criteriaa. General Anaesthesia case b. Prevention of shivering instead of treatment c. Intrathecal administration of drug.

Information sources PubMed, CINAHL, Cochrane, EMBASE, Google scholar and other grey literature databases will be searched for eligible studies. Two individuals independently assessed trial eligibility, abstracted data, and assessed the risk of bias. Bayesian network meta-analyses will be performed.

Main outcome(s)
1. Primary Outcome (drug efficacy)
a. Effective rate

b. Time to stop shivering
c. Recurrent rate of shivering
d. Effective rescue medication for shivering
2. Secondary Outcome (Adverse Effect):
a. Hypotension
b. Bradycardia
c. Sedation
d. Nausea
e. Vomiting.

Data management All raw paper (digital) will be stored in a cloud drive only accessible by investigator.

Quality assessment / Risk of bias analysis All eligible randomized control trial will go through (Revised Cochrane risk-of-bias tool for randomized trials) for risk of bias assessment and second screening with 2 investigator second screen after the RCTs went through the first screening for eligibility.

Strategy of data synthesis Statistical analysis plan
After data is collected in Microsoft Excel, subsequently will be analyse in R studio with bayesian network meta-analysis
-Data will be analyse base on Exchangeable dose effect model
* will be presented in rank heat plot to rank drug in interest in each of the efficacy domain and adverse effect domain
*Network diagram will be construct after data analysis for adverse event.

Subgroup analysis Network meta analysis taken into consideration of different dose effect as subgroup analysis.

Sensitivity analysis If there is an identifiable significant variable . sensitivity analysis will be done.

Language restriction No. But for standardization purpose, only officially translated journal into english will be acceptable, various of language/ contry in origin will still be accepted as long as translated officially bythejournal.

Country(ies) involved Malaysia.

Other relevant information Seach key word are divided into different part:
Mode of anaesthesia: Spinal anaesthesia, epidural anaesthesia, combine spinal epidural anesthesia, central neural axial, regional anaesthesia, neural axial block, spinal, subarachnoid block
Type of Studies randomized, control trials, compare,
Intervention: treatment, intravenous, IV,
Drugs: opioid, tramadol, pethidine, fentanyl, sulfentanil, remifentanil, morphine, alpha 2 agonist, clonidine, dexmedetomidine,5HT3, ondansetron, granesetron, palanosetron, NMDA, ketamine, Magnesium, Magnesium sulphate
*all keyword search with variance of spellings.

Keywords Shivering; post spinal anaethesia; epidural anesthesia; combine spinal epidural anesthesia;; treament; pharmacological intervention; pethidine; tramadol; dexmedetomidine; 5Ht3 antagonist; Magnesium sulphate.

Dissemination plans Study finding will be presented in Anaesthesia and Intensive care conferences and publish to indexed journal.

Contributions of each author
Author 1 - TREVOR KENG GUAN CHAN - Primary investigator, drafted the idea of the study, proposal, conduct search for the RCTs , getting raw papers, screening of RCTs (1st and 2nd screening), network meta analysis with R , manuscript writing, presentation in conference , publication.
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Author 2 - PUI SAN LOH - Guidance on proposal writing, input on inclusion and exclusion criteria, manuscript writing , guide on publication.
Author 3 - Sook Hui Chaw - Guidance on inclusion and exclusion criteria, statistical related issue , risk of bias assessment, R software programing , manuscript writing.
Author 4 - JEREMY SIN HUN TAN - RCTs search, screening of RCT (1st and 2nd screening) , Data Extraction, Risk of Bias assessment, Network meta analysis.
Author 5 - PUTERI JASMINE FLIZA FIRDAUS - RCTs search, raw paper procurement,, Data Extraction, Risk of Bias assessment, Network meta analysis.