International Journal of Psychosocial Rehabilitation, Vol. 24, Issue 08, 2020
ISSN: 1475-7192

A Comparative Study of Intrathecal Fentanyl And Dexmedetomidine For Prevention of Shivering After Spinal Anaesthesia In Caesarean Section

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Abstract--- *Background: One of the common problematic complications following spinal anaesthesia is shivering which causes discomfort and discontent. It can enhance demand for oxygen and increase in production of CO_2 about fourfold. Also, dexmedetomidine known to have sedative, analgesic, perioperative sympatholytic properties has shown effectiveness in suppressing postanesthesia shivering in patients. In comparison to intravenous route, intrathecal route focuses on the prevention of shivering rather than the control. Moreover, the administration of the drug combined with the spinal anaesthesia drug is more convenient and less time consuming and it promotes rapid onset of action. There is also less dose requirement with the intrathechal administration. Objectives: To compare the efficacy and safety of intrathecally administered fentanyl against dexmedetomidine in preventing post spinal shivering in patients posted for caesarean section under spinal anaesthesia. Methodology: All patients undergoing caesarean section will receive spinal anaesthesia in lateral or sitting position using 25G or 23 G Quincke needle in the L3-L4 intervertebral space via midline approach. After free flow of CSF, Group D will receive 10mg, 0.5% Bupivicaine (Heavy) combined with 5mcg dexmedetomidine in identical volume of 0.5ml, diluted with normal saline and Group F will receive 10mg (2ml), 0.5% Bupivicaine (hyperbaric) combined with 25ug (0.5ml) fentanyl Group F will receive 10mg (2ml), 0.5% Bupivicaine (hyperbaric) combined with 25ug (0.5ml) fentanyl. Results: We hypothesise lower incidence of shivering and prolong duration of post-operative analgesia in dexmedetomidine group compared to fentanyl group. Conclusion: We anticipate concluding Intrathecal dexmedetomidine has more efficacy and safety than intrathecally administered fentanyl in preventing post spinal shivering and need for post-operative rescue analgesia in patients posted for caesarean section under spinal anaesthesia. Keywords: Post spinal shivering, dexmedetomidine, fentanyl, spinal anaesthesia, caesarean section*

Keywords--- *Intrathecal, Fentanyl, dexmedetomidine,*

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Received: 19 Feb 2020 | Revised: 28 Mar 2020 | Accepted: 25 Apr 2020

I INTRODUCTION:

Spinal anaesthesia is frequently used for caesarean section. One of the common troublesome problems following spinal anaesthesia is shivering which causes discomfort and dissatisfaction.

Shivering causes discomfort for the patient and can interfere with monitoring of blood pressure, oxygen saturation and electrocardiogram. Hence, its prevention is rational and could result in better postoperative outcome.

Spinal anaesthesia decreases the vasoconstriction and also reduces shivering threshold.

Various pharmacological and non-pharmacological techniques have been tried for prevention of shivering but no gold standard has been determined yet. Intraoperative hypothermia can be reduced by techniques that limits loss of cutaneous heat to the surrounding environment such as those due to evaporation from surgical incisions, cold operating room and conductive cooling which is produced following administration of cold intravenous fluids. Warming of fluids, surgical drapes , ambient operation room temperature and active circulating water mattress have been used. Various drugs like pethidine, morphine, tramadol[1], clonidine[2], magnesium sulphate have been tried via intravenous route

Investigations related to dexmedetomidine [3] have proven it to have sedative, sympatholytic, hemodynamic-stabilizing and anesthetic-sparing analgesic properties. Also, effectiveness of dexmedetomidine [4] in suppression of postanesthesia shivering has been noted in patients; the shivering incidence was significantly lower in the dexmedetomidine group, and conclusions were made that intravenous dexmedetomidine[5] possesses antishivering properties and can reduce its occurrence via its highly selective alpha2 adrenergic receptor agonist properties.

Fentanyl [6] a highly ionized, lipophilic μ-receptor agonist is well known for its shorter duration and rapid onset of action following intrathecal administration. When administered intrathecally, the unionized component transfers rapidly into the spinal cord.

In comparison to intravenous route, intrathecal route focuses on the prevention of shivering rather than the control. Moreover, the administration of the drug combined with the spinal anaesthesia drug is more convenient and less time consuming and it promotes rapid onset of action. There is also less dose requirement with the intrathechal administration.

In the look out for safe and efficacious drug, in our study, we compare two safe drugs Dexmedetomidine and fentanyl [7], intrathecally for prevention of shivering in post spinal anaesthesia for patients posted for elective caesarean section [8] under spinal anaesthesia.

I.I. Primary objective:

To compare the incidence of shivering among both the drugs

I.II. Secondary objectives:

- Time interval from the administration of the drug to the onset of shivering if it occurs

- Severity of shivering if it occurs amongst the two study groups
- Adverse effects of both the drugs
- Duration of post-operative analgesia amongst the two study groups

Trial design: single group, exploratory

II METHODOLOGY:

A Prospective randomized comparitive study will be conducted on patients admitted to Acharya VinobhaBhave Hospital (AVBRH) Sawangi, Wardha during the period of 2019 to 2022 and will be the data source. The study will be conducted after obtaining approval from the ethics and screening committee of Jawaharlal Nehru Medical College, DMIMS (DU), Sawangi (M), Wardha.

Written and informed consent will be obtained from all the patients prior to procedure

Inclusion criteria:

- Parturient aged between 20-40 years
- Weighing 40- 80 kg
- ASA class I & II patients
- Patients scheduled for elective caesarean section
- All the patients willing for informed written consent

Exclusion criteria:

- Patients suffering from fever, drug allergy, thyroid disease and neuromuscular diseases
- Patients who develop shivering even before administering spinal anaesthesia
- Patients requiring supplementation with general anaesthesia
- Patients with renal disease and hepatic dysfunction

PREOPERATIVELY:

- A thorough history and general examination will be done for all the patients undergoing elective caesarean section.
- Pre-operative procedure will be explained to gain the confidence of the patients and we will take written consent.
- Patients scheduled for the operation will be kept fasting overnight
- Acid aspiration prophylaxis will be given : Ranitidine 150mg orally 12 hourly, one dose on the night before and the second dose on the morning of surgery will be given.
- Patients vital parameters will be evaluated such as pulse rate, respiratory rate, oxygen saturation (SpO2), ECG changes and blood pressure
- The selected patients will be randomly divided into two groups of 50 each.

On arrival of the patient to the operation theatre, patients will be co-loaded with Ringers Lactate solution after securing 18 G IV cannula. The baseline parameters will be recorded using monitors – ECG, SpO2, and NIBP. Baseline temperature will be recorded using a thermistor. Operation theatre temperature will be maintained at 280C

Spinal anaesthesia will be given to the patients in lateral or sitting position using 23 G Quincke needle in the L3-L4 intervertebral space via midline approach.All strict aseptic precautions will be followed. After the free flow of CSF is , Group D will receive 10mg, 0.5% Bupivicaine (Heavy) combined with 5mcg (0.1ml) dexmedetomidine in identical volume of 0.5ml, diluted with normal saline andGroup F will receive 10mg (2ml), 0.5% Bupivicaine (hyperbaric) combined with 25ug (0.5ml) fentanyl .

The incidence of shivering among the two drugs, time interval from administration of drug to shivering occurrence, intensity of shivering will be assessed at 1O minutes interval during the first one hour and then every half hourly during the surgery. Grade of Shivering as per Crossley and Mahajan given in table no.1

Patients will be closely monitored for undesired effects such as hypotension, sedation, bradycardia, respiratory depression, nausea, vomiting and itching. Sedation will be scored according to Ramsay sedation scale give in table no.

The efficacy of post operative analgesia will be determined by VAS score and time required for rescue anaesthesia in post operative period will be noted.

Sample

Following neuroaxial[9] block median incidence of shivering is 55%. A sample size of 50 patients each is calculated by using www.openepi.com to have at least 80% power and an alpha of 0.05 to detect the expected differenceamong the groups with respect to the primary goal of reuction in incidence of shivering.

Expected Outcomes/Results:

Intrathecal administration of dexmedetomidine has more efficacy and safety in prevention of post spinal shivering and enhances duration of postoperative analgesia in patients undergoing ceasrean section

III DISCUSSION:

Fentanyl a lipophilic opioid and is an agonist at μ-receptor. Both fentanyl and dexmedetomidine [10] have shown to improve the quality of intraoperative analgesia and hemodynamic stability. The α-2 adrenergic agents have antishivering property and will show significant reduction in the incidence of shivering between the two groups. Also, dexmedetomidine is known to produce more prolonged motor and sensory block and good patient satisfaction as compared with 25 μg fentanyl .

Interpretation: Dexmedetomidine can be an attractive alternative to fentanyl as an addition to spinal bupivacaine [11] in surgical procedures to reduce incidence of shivering and to increase the duration of need of rescue analgesia post operatively. A number of other studies in this region related to this study were reviewed [12-80].

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Received: 19 Feb 2020 | Revised: 28 Mar 2020 | Accepted: 25 Apr 2020

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Received: 19 Feb 2020 | Revised: 28 Mar 2020 | Accepted: 25 Apr 2020