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Intraoperative Infusion of Dexmedetomidine versus Lidocaine or Magnesium Sulphate for Enhanced Quality of Recovery After Spine Surgery Fixation

Protocol of Paper Submitted in Partial Fulfilment of Research in Anesthesia, Intensive Care and Pain Management

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Introduction

Thoracolumbar fixation is a major spine surgery; it is performed to stabilize the spine after trauma, deformity or advanced degenerative disease. The primary surgical goals are to restore spinal alignment and achieve solid arthrodesis (fusion). From a surgical view, success is often measured by radiographic outcomes, hardware integrity and fusion rates. As anesthesiologists, we must recognize that technical success does not the same as optimal patient recovery [1].

This is why the concept of Quality of Recovery (QoR) becomes very important. QoR is a patient-centered outcome that covers more than the absence of surgical complications. It includes: rapid return of physical function, pain control, psychological well-being, emotional stability and Patient satisfaction [2].

Therefore, our focus in the perioperative care shifts the focus from "did the surgery succeed?" to "how we can help the patient to recover physically, mentally, and functionally?" This approach is measured using patient-reported outcomes such as the QoR-15 or QoR-40 questionnaires.

Dexmedetomidine (Precedex) has become one of the most valuable medications in modern anesthesia, especially for surgeries associated with significant pain. As a highly selective α2-adrenergic agonist, dexmedetomidine provides a unique combination of analgesia, anxiolysis, and cooperative sedation without causing respiratory depression; it is helpful during painful procedures such as spine surgery.

When infused intraoperative; Precedex reduces central sensitization and diminishes the stress response to surgical stimuli, resulting in improved intraoperative hemodynamic stability, lower postoperative pain scores, reduced opioid requirements, and a smooth and calm recovery from anesthesia [3].

Intraoperative intravenous lidocaine infusion has become an important tool for improving postoperative pain control; especially in major surgeries. Although lidocaine is commonly known as a local anesthetic, when given systemically during surgery it works in several meaningful ways: it calms the central nervous system, reduces the body's inflammatory response to tissue trauma, and decreases pain sensitivity that often appears after anesthesia wears off [4].

Because of these combined effects, patients who receive IV lidocaine typically experience lower postoperative pain scores and need less opioid medications; therefore, avoid many opioid-related side effects such as nausea, sedation and constipation.

Lidocaine infusion not only reduces early postoperative pain but also help for faster recovery, earlier mobilization, and improved overall patient satisfaction [5].

Magnesium sulfate has become an increasingly valuable tool for anesthesiologists caring for patients undergoing long and painful surgical procedures. During major surgeries, the body's stress response can increase pain and make anesthetic management more challenging [6].
Magnesium works by blocking NMDA receptors, which are the key player in central sensitization and postoperative hyperalgesia. This means patients wake up with less pain, lower opioid requirements, and often more stable intraoperative vital signs. Many doctors preferred to use magnesium sulphate because it is inexpensive, widely available, and easy to administer as a slow infusion [7].

Rational

Spine surgery often results in moderate to severe pain, delayed mobility, sleep disturbance, and gastrointestinal issues, making quality of recovery a key measure for evaluating multimodal interventions.

Studying quality of recovery after spine surgery provides critical insights into patient-focused results beyond traditional metrics like pain scores, focusing on functional recovery, emotional well-being, sleep quality, and overall satisfaction using validated tools like Quality of Recovery-40. Quality of Recovery-40 includes how the patient feels in the hours and days after surgery: their pain level, ability to move, emotional well-being, sleep quality, and overall satisfaction.

This study will be conducted in Zagazig University hospitals to assess the quality of recovery-40 (QoR-40) after spine fixation using intraoperative infusion of dexmedetomidine versus lidocaine or magnesium sulphate.

Research Question

Is there is a difference in the quality of recovery between intraoperative infusion of dexmeditomidine, lidocaine and magnesium sulphate after spine surgery fixation?

Hypothesis

Null hypothesis (H0):

There is no difference in the quality of recovery between intraoperative infusion of Dexmeditomidine, Lidocaine and Magnisium sulphate during spine fixation regarding their effect on post-operative Quality of Recovery-40.

Alternative hypothesis (H1):

There is a difference between in the quality of recovery between intraoperative infusion of Dexmeditomidine, Lidocaine and Magnisium sulphate during spine fixation regarding their effect on post-operative Quality of Recovery -40.

Aim of the work

Improving Quality of Recovery -40 after spine surgery fixation by comparing intraoperative infusion of dexmedetomidine, lidocaine or Magnesium sulphate.

Objectives

To compare the postoperative Quality of Recovery -40 between patients who received intraoperative infusion of dexmedetomidine, lidocaine, or magnesium sulphate during elective spine fixation surgery (as primary outcome), regarding post-operative pain intensity, time to first rescue analgesia and compare total opioid consumption in the first 48 h post-operative (as secondary outcomes).

PATIENTS AND METHODS

- **Technical Design:**

Site of study*:*

This study will be carried out in Anesthesia, intensive care and pain management department in neurosurgical theater in Zagazig University Hospital safter approval of Institutional Review Board (IRB).

Duration of the study:

This study will be carried out within a period of 6-12 months.

Sample size:

By assuming that quality of recovery scoring among lidocaine group and the placebo group was 118+13.5 and 110+15, respectively [8].

Sample size is calculated to be 117 cases divided into three groups each group of 39 patients, with a 95% confidence interval and a power of 80% by using Epi Info version 6.

Inclusion criteria:

1- Patient acceptance.

2- Patients age between 18-60 years old.

2- Both sexes.

3- Physical status from ASA I to III.

4- BMI $\geq$ 18 kg/m^2 & $\leq$ 35 kg/m^2.

5- Patient acceptance with written consent.

6- Elective lumbar fixation double level surgery.

Exclusion criteria:

1- Uncooperative patient.

2- Allergy to study drugs.

3- Patients on chronic alcohol, opioid, tranquilizer or sedative use.

4- Pregnancy.

5- Emergency surgery

Withdrawal criteria:

The patient has the right to withdraw from the study at any time without any negative consequence on his medical or surgical treatment plan.

- **Randomization:**

  The patients will be recruited before admission in the preoperative anesthesia clinic. The study details will be explained before obtaining written informed consent. Patients will be randomly allocated to three groups using computer-generated randomization tables, the randomization sequences were concealed in sealed envelope

Operational design:

Type of study: Prospective, Randomized, double blind Clinical Study

Blindness: both patient and follow-up anesthesiologist will be blind.

Study groups:

i. -**Group (L):** the patient will receive lidocaine IV infusion, loading dose (1.5 mg) diluted in 10 cm 0.9% saline given bolus then (1.5-2 mg/kg/h) will start after induction of anesthesia until the end of surgery.

ii. -**Group (D):** the patient will receive Dexmedetomidine IV infusion, loading dose (0.5 -1 mcg/kg) diluted in 10 cm 0.9% saline given bolus then (0.2-0.7mcg/kg/h) will start after induction of anesthesia until the end of surgery.

iii. **-Group (M):** the patient will receive Magnesium sulphate IV infusion, loading dose (30 mg/kg diluted in 10 cm 0.9% saline over 10-30 min than 6-20 mg/kg/h) will start after induction of anesthesia until the end of surgery.

- **Anesthetic technique:**

(a) Preoperative assessment in the holding area:

- Written informed consent will be obtained from all patients.
- Preoperative assessment will be carried out by full medical, surgical, family, and medications history. Complete clinical examination as well as laboratory investigations (complete blood count (CBC), liver function test (LFT), kidney function test (KFT), coagulation profile (PT, PTT, INR) and random blood glucose (RBG).
- Vital signs of the patients will be measured and recorded (Heart Rate, Blood Pressure & SPO2).
- Asking about fasting more than 8 hrs. for heavy fatty meal, 6 hrs. for light meals& 2 hrs. for clear fluids preoperative.
- Insert peripheral IV 20 G line.
- Start sedation with midazolam (0.1mg/kg) 10 min before shifting to operating room and connect the patient to oxygen mask.

(b) On Arrival at the operation room:

- Patient will remain on the operation trolley.
- Patient connected to standard monitors (five leads ECG, NIBP, pulse oximeter & capnography) take basal readings and vital signs will be recorded every 5 minutes.
- Start IV fluid (ringer lactate 8-10 ml/kg).
- Antibiotics will be given to the patient.

(c) Induction of anesthesia for all groups:

- Start preoxygenation of the patient.
- Induction will be started by Fentanyl (1-2 mcg/kg), Propofol (2-2.5 mg/kg), Rocuronium (0.6-1 mg/kg) and intubation done by suitable size endotracheal tube which will be confirmed in the correct positione and will be secured.
- Inhalation anesthesia will be started by isoflurane at 1.2%, then adjust the mechanical ventilation to maintain normocapnia (paco2 35-45 mmhg).

- Another IV line inserted; lidocaine, dexmedetomidine or magnesium sulphate will be connected to the patient and started.

(d) Intraoperative period:

- All Patient will be shifted to operating table by 5 persons in prone position.
- Patient position secured, without any compression on the face.
- Endotracheal tube position re-checked.
- Anesthesia will be maintained in all groups by isoflurane 1.2% and maintenance doses of rocuronium (0.1-0.2mg/kg) guided by neuromuscular monitoring.
- IV fluid will be given as calculated according to the body weight of the patient and replaced by crystalloid, colloid or blood according to the patient condition.

(e) At the end of surgery:

- Isoflurane will be discontinued.
- All intravenous medication will be stopped.
- Patient will be shifted to supine position.
- Reversal of muscle relaxant will be done by sugamadex 2 mg/kg for moderate block and 4 mg/kg for deep block.
- Patient will be extubated after fulfilling the criteria of extubation and will be Shifted to post anesthesia care unit (PACU) in slight head up position, on oxygen mask and connected to the monitor.
- All patients received paracetamol as standard intravenous infusion analgesia at dose of 15mg/Kg every 8 hours (maximum dose: 4 g / day).
- For postoperative data collection, the time of PACU admission will be regarded as time 0.
- Before moving to the ward, the patient will be monitored in the PACU, for an hour for (HR& MAP). Thirty minute following admission to PACU, both HR and MAP will be recorded.

(f) In the neurosurgical word:

-pain intensity assessed by visual analogue scale (VAS) ranges from '0' representing one pain extreme (no pain") to '10' representing the other pain extreme (pain as bad as you can imagine" or "worst pain [9], at 2,4,6,8,12,18,24,48 hours post operatively if it's equal or more than 3 rescue analgesia (nalbuphine 20 mg will give slowly IV over 2-3 min as single maximum dose with maximum daily dose 160 mg/day) is given till 48 h postoperative.

- After 24 h after surgery, patient will answer the questioner of QoR-40 after 24 h after surgery

QoR -40 Questioner: [10]

The QoR-40 contains 40 questions grouped into 5 dimensions:

1. <u>Physical Comfort (12 items)</u>

1. Able to breathe easily
2. Have had good sleep
3. Have felt comfortable
4. Have had a good appetite
5. Able to enjoy food
6. No nausea
7. No vomiting
8. Feeling rested
9. Feeling warm and comfortable
10. No shivering
11. No sweating
12. Have had good general comfort

2. <u>Emotional State (9 items)</u>

13. Been able to feel relaxed
14. Been in control
15. Been able to enjoy company of others.
16. Felt anxious
17. Felt angry or irritable
18. Felt depressed
19. Felt lonely
20. Felt confused
21. Felt frightened

3. Physical Independence (5 items)

22. Able to look after personal toilet and hygiene unaided
23. Able to write (or use your phone)
24. Able to speak normally
25. Able to wash yourself
26. Able to dress yourself

4. Psychological Support (7 items)

27. Able to communicate with family or friends
28. Able to communicate with hospital staff
29. Feeling supported by hospital staff
30. Feeling understood by others
31. Feeling supported by family or friends
32. Feeling able to share worries or concerns
33. Feeling encouraged by others

5. Pain (7 items)

34. Moderate pain
35. Severe pain
36. Headache
37. Muscle pains
38. Back pain
39. Sore throat
40. Pain affecting sleep

Scoring

Each item is scored on a 5-point Likert scale:

1 = None of the time
2 = Some of the time
3 = Usually
4 = Most of the time
5 = All of the time

Total score range: 40–200

- 150-200 --- excellent recovery
- 140-159 --- good recovery
- Less than 140 --- moderate recovery

Data collection

From each patient the following data will be collected:

- Patient's characteristics include age, sex, BMI, ASA physical status and side laterality of the procedure.
- Operative data which include how many spine levels are included in the fixation, and duration of surgery.
- Intra and postoperative vital signs.
- Total amount of the study infusion medications given.
- pain intensity using visual analogue score at 2,4,6,8,12,24,48 hours after surgery.
- Time to first dose of rescue analgesia (nalbuphine) and total amount within first 48 hrs.
- QoR -40 Questioner score at 24 h postoperative.
- Side effects of medications as, bradycardia, hypotension , sedation.

If bradycardia occurred(decrease HR < 50 beats per min) will be recorded and treated with 1mg atropine.

If hypotension occurred (decrease MAP 20% from the baseline) will record and treated with vasoactive agents – especially vasopressors as ephedrine and fluids will be given.

Sedation of the patient can be evaluated by Modified Ramzy sedation score in where Level 1 patient is awake and alert, Level 2 patient is awake with purposeful response to verbal command, Level 3 patient appears sleepy with purposeful response to verbal command, Level 4 patients appear sleepy with purpose response to louder command, Level 5 patient appears sleepy with sluggish response to verbal command (11)

- Patient satisfaction score using **5-point Likert scale**(12)

  5 = Very Satisfied

  4 = Satisfied

  3 = Neutral

  2 = Unsatisfied

  1 = Very Unsatisfied

Outcome

Primary Outcome

Quality of Recovery-40 (QoR-40) score measured at 24 hours postoperatively

Secondary Outcomes

- Time to first rescue analgesia
- Total opioid consumption during the first 24 and 48 hours
- Number of rescue analgesic doses
- PACU length of stay
- Postoperative nausea and vomiting (PONV)
- Excessive sedation (e.g., Ramsay Sedation Score)
- Respiratory depression.
- Bradycardia
- Patient satisfaction score at 24 or 48 hours

Administrative design

- Approval will be obtained from Institutional Review Board (IRB) Zagazig University.

-Written informed consents will be obtained from all patients in pre-Anesthesia visit after explanation of the study details.

Results

Collected data will be presented in tables and suitable graphs and analyzed according to standard statistical methods.

Discussion

Discussion will be done on results compared to related relevant literature, and scientific research.

Conclusion and Recommendations

These will be derived from the findings of the study.

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