Official title

Comparative study of the effect of continuous caudal epidural with general anaesthesia versus general anaesthesia on intra operative and post operative analgesic requirements for lumbar fixation

DOCUMENT DATE:
APRIL 9, 2025

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Thesis

Submitted for Partial Fulfillment of M.D. Degree
in **Anaesthesiology, Intensive Care and Pain Management**

By

Postgraduate Student: Esraa Abd El-Latif Mohamed Shawky
***Degree**: M.B.B.CH., M.Sc., (Ain-Shams University)*

Under Supervision of

DIRECTOR: Dr. Mahmoud Abd El-Aziz Ahmed Ghallab
***Academic Position**: Professor of Anaesthesia, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University*

CO-DIRECTOR: Dr. Ahmed Mohamed El-Sayed El-Hennawy
***Academic Position**: Professor of Anaesthesia, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University*

CO-DIRECTOR: Dr. Paula Micheal El-Komos Samaan
***Academic Position**: Lecturer of Anaesthesia, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University*

CO-DIRECTOR: Dr. Omar Mohamed Zafer Mohamed
***Academic Position**: Lecturer of Anaesthesia, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University*

What is already known on this subject? AND What does this study add?

Caudal epidural anaesthesia has been used successfully in adult patients either as primarily sole anaesthetic technique or adjuncts to general anaesthesia to provide post operative analgesia. Pre-emptive caudal epidural is a proven technique for providing analgesia for spinal surgeries. Challenging aspect of spine surgery is to provide extended post operative analgesia.

This study is designed to evaluate the effectiveness of continuous caudal epidural for intra operative analgesia as alternative to opioid analgesia in general anaesthesia and reducing post operative opioid requirements to control post operative pain.

1. INTRODUCTION/ REVIEW

Pain control during intra operative and post operative period for spine surgeries is crucial in patients as poor pain control may result in morbidity and mortality **(Fawzi &Almarakbi, 2012)**. Severe acute pain prolongs hospital stay, delays mobilization and promotes subsequent chronic post-surgical pain **(Schug &Bruce, 2017)**.

Whilst general anaesthesia is commonly used to undertake spine surgery, the use of neuraxial and peripheral regional anaesthesia techniques for intra operative and post operative analgesia is an evolving practice **(Gerbershagen et al., 2013)**. Multimodal analgesia, including opioids, is used to limit pain after spinal surgery. Common adverse effects of opioids include nausea, constipation, ileus, delirium, itching, respiratory depression and respiratory tract infection **(Eochagain et al., 2022)**.

Caudal anaesthesia was described in 1901 by two French physicians, Fernand Cathelin and Jean-Anthanase Sicard (**Waurick & Waurick, 2015**). The caudal epidural block was first introduced as a landmark-based, blind technique. Success rate in adults was 68–75% even in the experienced hands. Because of the inaccuracy of blind technique, some authors have recommended that caudal epidural injection is performed under fluoroscopic guidance **(Barham &Hilton, 2010)**. Continuous caudal analgesia was first applied clinically, in 1941, being used to relieve pain for an

operation upon the lower extremity **(Kao & Lin, 2017)**. Caudal epidural anaesthesia/analgesia is the most widely employed technique for various surgical procedures within the distribution of T10–S5 dermatome and it is easier to perform caudal procedure in the prone position **(Hurley, 2010)**.

Caudal analgesia is a good, reliable and easy method to provide intra operative and post operative analgesia. However, the single shot caudal analgesia is short in duration, so the catheter injection may be used to prolong the analgesia time as continuous caudal epidural **(El-Feky &Abd El Aziz, 2015)**.

Caudal epidural analgesia, as pre-emptive analgesia, is an underutilized technique in adult patients undergoing lumbosacral spine surgeries. Caudal epidural block before surgery acts by blocking sensory input at the spinal cord level. Thus, pre-emptive analgesia has an important role in providing effective pain relief after lumbosacral spine surgeries **(Al Oweidi et al., 2010)**. The combined caudal epidural analgesia with general anaesthesia is a proven technique in providing analgesia and managing post operative pain in lumbar spine procedures **(Lakshminarasimhaiah G et al., 2018)**. It provides prolonged pain relief with adequate sensory block and limited motor blockade for early mobilization **(Nagappa et al., 2018)**.

Among all available local anaesthetic bupivacaine is most commonly used. It produces a denser sensory block and enables better control of sensory and motor blockade while having the least incidence of an incomplete block **(Benyahia et al., 2015)**.

Common complications associated with caudal anaesthesia include: Subdural, intravascular, or intraosseous injection, infection, hypotension, nerve roots injury, rectum perforation, hematoma formation, local anaesthetic toxicity, delayed respiratory depression, urinary retention, sacral osteomyelitis **(Wiegele et al., 2019)**. A devastating complication of a caudal block is total spinal anaesthesia that can occur from an inadvertent dural puncture with subsequent intrathecal injection of local anaesthetic. Also, caudal epidural blocks have a higher incidence of local anaesthetic-related seizures **(Schug & Bruce, 2017)**.

The overall benefit of intravenous analgesia versus caudal analgesia is still controversial, although many studies have shown that caudal epidural analgesia provides superior post operative analgesia compared to intravenous analgesia **(Kumar et al., 2017)**.

In this clinical study, we will justify the current practice of combined continuous caudal epidural with general anaesthesia in adult patients undergoing lumbar fixation versus general anaesthesia. Furthermore, we will determine the analgesic

requirement, rescue analgesia, hemodynamic changes and possible complications with continuous caudal epidural analgesia.

2. AIM/ OBJECTIVES

The aim of this study is to evaluate the effectiveness of combined continuous caudal epidural with general anaesthesia versus general anaesthesia for intra operative and post operative analgesia in patients undergoing lumbar fixation, by recording intra operative and post operative analgesic requirements, blood pressure and heart rate and post operative patient-reported pain on the numeric pain scale score.

3. METHODOLOGY:

Patients and Methods

- **Type of the study:** Interventional, prospective, comparative randomized clinical trial.
- **Study Setting:** The operating theaters of Ain Shams University Hospitals.
- **Study period:** Over six months, after the approval of Medical Research Ethical Committee.
- **Study population:**

Inclusion criteria:

- Age group: Adult patients from age of 21 years to 60 years
- Sex: Both sexes.
- ASA Classification: patients with ASA classification I, II.
- Elective lumbar fixation surgeries.

Exclusion criteria:

- Patients refuse to give informed consent.
- Patients younger than 21 or older than 60.
- History of bupivacaine allergy.
- Emergency surgeries.
- Patients who underwent previous spine surgeries of any cause.

- Infection at the site of injection.
- Coagulopathy (acquired, induced, genetic).
- ASA Classification: ASA III, IV.
- Severe aortic stenosis, severe mitral stenosis, hypertrophic obstructive cardiomyopathy.
- Severe hypovolemia, Severe uncorrected anemia.
- Increased intra-cranial pressure (i.e., brain tumor or recent head injury).

Sampling method:

Patients will be randomly allocated by computer generated randomization into two equal groups A and B.

- **Group A:** Patients doing lumbar fixation with combined continuous caudal epidural and general anaesthesia.
- **Group B:** Patients doing lumbar fixation under general anaesthesia (opioid analgesia).

Sample size justification:

Using PASS 15 program for sample size calculation and according to (**Abdelhady et al., 2022**), the expected mean intra-operative narcotic consumption among study groups is 186.5 ± 21.6 µg and 106 ± 16.4 µg.

Sample size of 30 patients per group can detect the difference between two groups with power >90% and alpha error 0.05.

Ethical considerations:

The study protocol will receive ethical approval from the Medical Research Ethical Committee, Faculty of Medicine, Ain Shams University. Informed written consent will be obtained from each patient before patients' allocation.

Study Procedures:

Patients will be randomly allocated into two equal groups.

<u>Preoperative setting</u>:

- Pre-operative assessment will be done by accurate history taking, full physical examination, laboratory and radiological investigations. including complete blood count (CBC), liver function test (LFT), kidney function test (KFT), prothrombin time (PT) and partial thromboplastin time (PTT) will be checked.
- All patient will be fasting for 8 hours pre operative.
- All patients will be informed about the study design, objectives and techniques.

- Informed consent will be signed by every patient prior to inclusion in the study.
- All patients will be educated about numeric pain scale score which 0 means no pain and 10 means worst imaginable pain.

Intraoperative setting:

- Standard perioperative monitoring will include pulse oximetry, electrocardiogram, end-tidal CO_2 measurement, inhaled volatile agent concentration and non-invasive blood pressure measurement.
- Baseline parameters such as oxygen saturation, systolic, diastolic and mean blood pressure, heart rate will be observed.
- Intravenous line will be inserted.
- For all patients, general anaesthesia will be induced by intravenous route using midazolam 0.04 mg/kg, fentanyl 1 µg/kg, propofol 2 mg/kg, atracurium 0.5 mg/kg.
- This will be followed by endotracheal intubation and mechanical ventilation. Maintenance of anaesthesia will be achieved by isoflurane 1.5% in oxygen and air (50:50) and atracurium 0.1 mg/kg every 20 minutes, so as to maintain end tidal CO_2 between 35 to 40 mm Hg.
- Intra operative heart rate and mean blood pressure will be recorded. Estimated blood loss will be determined.

Group A: (continuous caudal epidural with general anaesthesia "study group")

- After induction of anaesthesia as mentioned above, patients will be located in the prone position for caudal epidural block. Sterile skin preparation and draping of the entire region will be completed in the standard fashion.
- Fluoroscopy will be utilized and a lateral view will be obtained to demonstrate the anatomic boundaries of the sacral canal. With fluoroscopy, the caudal canal will appear as a translucent layer posterior to the sacral segments. The median sacral crest will be visualized as an opaque line posterior to the caudal canal. The sacral hiatus will be visualized as a translucent opening at the base of the caudal canal. The coccyx will be seen articulating with the inferior surface of the sacrum. A 17- or 18-gauge Tuohy-type needle will be inserted in the midline into the caudal canal. A feeling of a slight "snap" may be appreciated when the advancing needle pierces the sacrococcygeal ligament. Once the needle reaches the ventral wall of the sacral canal, it will be withdrawn and reoriented, directing it more cranially (by depressing the hub and advancing) for further insertion into the canal. The anteroposterior view will be used once the epidural needle is safely situated within the canal and the

epidural catheter will be advanced cephalad. In this projection, the intermediate sacral crests will appear as opaque vertical lines on either side of the midline. The sacral foramina will be visualized as translucent and nearly circular areas lateral to the intermediate sacral crests. Once the correct placement of the needle will be confirmed, a catheter will be inserted into the desired location while depth and position will be confirmed fluoroscopically.

- Before the local anaesthetic will be injected, careful aspiration or passive drainage is essential to exclude an unintentional intravascular or intrathecal needle location. An initial dose of 20 ml of 0.25% bupivacaine will be injected in the caudal canal in order to perform sensory block and spare motor power. Then a dose of 10 ml 0.25% bupivacaine will be injected through the epidural catheter every 1-hour intra operatively and at 0-hour and 1-hour post operative. Then the catheter will be removed 1 hour post operative.

Group B: (general anaesthesia "control group")

- General anaesthesia will be induced as described above with administration of extra doses of fentanyl as needed according to hemodynamic changes suggesting pain sensation.

Post-operative setting:

- After completion of surgery, the residual neuromuscular block will be reversed with injection of neostigmine 0.05 mg/kg and atropine 0.01 mg/kg. When patients become suitable for extubation, with stable hemodynamic and adequate muscle power, thorough oral and endotracheal suction followed by extubation will be done.
- Patients will be nursed in post anaesthesia care unit for monitoring of post operative vital signs and for post operative pain assessment by numeric pain scale score at 0-hour and management accordingly.
- Patients postoperative pain will be followed up at the ward at time interval 0, 1, 2, 4, 6 hours.
- Patients will undergo close monitoring for the first 6 hours after caudal injection for overdose or adverse reactions.

- The following factors will be assessed:
  (1) Intra operative heart rate and blood pressure.
  (2) Post operative pain assessment according to numeric pain scale score 1-10 as (0= no pain, 10 =worst imaginable pain) and hemodynamic parameters at 0, 1, 2, 4, 6 hours.
  (3) Time to rescue analgesia (intravenous analgesia administered after

surgery) when the numeric pain scale score is 3 or higher. Patients with numeric pain scale score ≥ 3 at any point of time, will receive intravenous morphine 5mg.

(4) Estimated blood loss and surgeon satisfaction of surgical field.

(5) Total intra operative and post operative analgesia in both groups.

(6) Common complications of caudal block in the postoperative period which include hypotension, bradycardia, lower limb numbness and urinary retention. These complications will be recorded and managed accordingly.

Measured outcomes:

Primary outcome:

- Determining the total amount of fentanyl that will be consumed as intra operative analgesia.

Secondary outcome:

- Determining the total amount of morphine that will be given as analgesia for the first 6 hours post operative.
- Analyzing the numeric pain scale score for the first 6 hours post operative.
- Detecting effect of continuous caudal epidural analgesia on intra operative and post operative hemodynamic changes.
- Identifying the time to the first demand for rescue analgesia.
- Justifying the use of continuous caudal epidural for analgesia in lumbar fixation surgeries.

Statistical analysis:

- Statistical analysis will be carried out using the statistical software SPSS program. Description of quantitative data as mean and standard deviation and qualitative data as number and percentage.
- Comparison between the two groups will be done by using the Chi-square test, independent t-test or Mann–Whitney U-test according to the distribution of data. A p-value less than 0.05 will be considered statistically significant.

End point:

- Severe hemodynamic instability due to any surgical complication.
- Any surgical emergency that will need to reopen the patient in operating room.

- 6 hours post operative.

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