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

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Informed consent form

Ain Shams University

Faculty of Medicine

Ethical Committee of Scientific research

Informed consent form for patients who are invited to participate in the research

Patient name: Age: Sex:

Research title:

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

2023-2024

Introduction and aim of the work:

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. Multimodal analgesia, including opioids, is used to limit pain after spinal surgery.

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 prone position. 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.

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. The combined caudal epidural analgesia with general anaesthesia is a proven technique in providing analgesia and managing post operative pain in lumbar spine procedures. It provides prolonged pain relief with adequate sensory block and limited motor blockade for early mobilization.

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.

- **Type of the study:** Interventional, prospective, comparative randomized clinical trial.
- **Study Setting:** The operating theaters of Ain Shams University Hospitals.
- **Study period:** Over four to 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).

Ethical considerations:

The study protocol received 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.

Preoperative setting:

- 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.

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.

Number and Selection of participants:

- 60 participants, 30 participants are patients undergoing continuous caudal epidural with general anaesthesia for lumbar fixation and 30 participants are patients undergoing general anaesthesia for lumbar fixation.

Benefits expected from the study:

Benefits to the participants:

There will be accurate preoperative investigation and postoperative follow up for all participants. The patients who will do combined continuous caudal

anaesthesia with general anaesthesia for lumbar fixation will undergo with least opioid and ideal intra operative and post operative pain control. The control group with general anaesthesia will be followed and adequate intra operative and post operative pain control with opioid analgesia.

Benefits to the community:

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.

Risks and complications:

This research will not expose your patient to further risks or complications despite the standard risks of protocol of Ain Shams University hospitals.

- ***The risk of blood sampling:*** The pre operative blood sample for routine investigations will be obtained by a trained, professional nurse using sterile, disposable equipment. The risks of bleeding, bruising, or infection are small, and similar to having blood drawn at your doctor's office. However, the volume of blood (5 milliliters) is small, and will be replaced quickly by your body.
- ***The risk of continuous caudal epidural:*** Subdural, intravascular, or intraosseous injection, infection, hypotension, nerve roots injury, rectum perforation, hematoma formation, local anaesthetic toxicity, delayed respiratory depression, urinary retention, sacral osteomyelitis. A rare but serious complication 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. Intra operative and Postoperative follow up for all participants to exclude them and early management.

Reimbursements in cases of risks and complications:

Should your patient get physically injured as a result of research-related procedures, Esraa Abd El-latif Mohamed Shawky will provide first-aid management and resuscitation even if the patient will be excluded from the research.

Conducting the consent:

The consent will be conducted to the patient by the investigator, Esraa Abd El-latif Mohamed Shawky in the Anaesthesia, Intensive care and pain management Department, Ain Shams University Hospital. Literate individuals will be left to read the consent followed by its explanation by the mentioned

investigator, while illiterate individuals will have the consent read and explained to them as well.

Alternatives to participating:

In case of refusing to participate in this research, the patient will be followed up and will receive his treatment as planned.

Confidentiality:

You will deal in complete confidentiality, and no one has right to read your patient medical information except the main researcher. After the research is complete, you will be informed regarding your patient's research results and also further information regarding your patient's health status.

Right to refuse or withdraw:

Any participant doesn`t have to take part in this research if he/she or want. They may also stop participating at anytime. If you have read this form and have decided to let your patient to participate in this study, please understand that your patient's participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which your patient is otherwise entitled. Your decision whether or not to participate in this study will not affect your patient's medical care. Individual privacy will be maintained in all published and written data resulting from the study.

Contact Information:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the investigator, Esraa Abd El-latif Mohamed Shawky at phone number: 42180513, mobile number: 01119895491. You can also call the ethical committee supervisor Prof. Dr. Nermeen Sadek Nasr Abdelmalek at mobile phone number: 01225585593. If you have any problems or concerns about the study, you can also call the main supervisor Prof. Dr. Mahmoud Abd El-Aziz Ahmed Ghallab at mobile phone number: 01221625868.

You do not have to sign this consent form. But if you do not, your patient will not be able to participate in this research study.

Certificate of consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I ask have been answered to my satisfaction. I consent voluntary to participate in this research and understand that I have the right to withdraw from the research at any time without in any way affecting my patient`s medical care.

- Name of participant:…….
- Signature of participant or legal guardian:……
- Identity number or finger print: ……

- Date:……...

I have accurately read or witnessed the accurate reading of the consent to the potential participant. The individual has had the opportunity to ask questions I confirm that the individual has given consent freely.

- Name of researcher: Esraa Abd El-latif Mohamed Shawky
- Signature of researcher:……
- Date:…….

This proposal has been reviewed and approved by Ethical Committee of Scientific research, which is a committee whose task is to make sure that research participants are protected from harm.

If you wish to find more about Ethical Committee of Scientific research. Contact:
Name:
Address:
Telephone number: