Effect of Spinal Anesthesia with Bupivacaine versus Prilocaine on Shivering in Patients Undergoing Inguinal Hernia Repair: A Randomized Double-Blind Study

Background

Inguinal hernia is the most common type of abdominal hernia, more common in men than women. Inguinal hernia repair is performed under general, spinal anesthesia or local anesthesia. [1]

Core body temperature is normally tightly regulated to within a few tenths of a degree. The major thermoregulatory defenses in humans are sweating, arteriovenous shunt vasoconstriction, and shivering. [2]

Spinal anesthesia is considered a safe anesthetic technique for the surgery, however 40 to 60 percent of patients' experience shivering due to vasodilatation, which facilitates rapid heat loss and causes a redistribution of body heat from the core to peripheral tissue. However, perioperative heat loss due to exposure of skin, evaporation from exposed sites, cold intravenous fluids, contribute to factors that predispose shivering. Postoperative shivering can be either thermos-genic with hypothermia or nonthermogenic associated with pain modulation and surgical stress. [3]

Shivering is considered undesirable, as these random spontaneous, asynchronous skeletal muscle contractions increases the basal metabolism with increase in oxygen consumption up to be 600% hypoxemia, metabolic acidosis, triggering myocardial ischemia, increased wound pain, delayed wound healing, as well as increase in blood pressure, intraocular and intracranial pressure. [4-8]

Bupivacaine is a long acting local anesthetic belonging to the amide group it is more stable and less likely to cause allergic reactions among other local anesthetics however; it delays hospital discharge in ambulatory surgery. Prilocaine is a local anesthetic belonging to the amide group with rapid onset, intermediate potency, and action. [9]

The old local anesthetics prilocaine was reintroduced in the market as hyperbaric prilocaine 2% which provides anesthesia for 75–90 minutes after spinal administration [10], thus increasingly used in the ambulatory setting [11].

Since bupivacaine 0.5% has significantly prolonged postoperative analgesic duration versus prilocaine 2% [12], thus We hypothesis that bupivacaine may have a superior effect on minimizing postoperative shivering through providing better analgesia.

The main aim of this study is to compare spinal anesthesia with prilocaine 2%, versus bupivacaine 0.5% on postoperative shivering during repair of inguinal hernia.

Primary outcome is comparing postoperative shivering by assessing thegrade of shivering severity using a scale of Bedside Shivering Assessment Score (BSAS). [13,14]

Secondary outcomes will include hemodynamic parameters intraoperative and postoperative pain scores. Onset and regression of sensory and motor block, motor and sensory block duration, need for intraoperative opioid and or sedation time to discharge. Occurrence of other adverse events will also be recorded.

Patients and methods

After Ethics Committee approval and patients' written informed consent, 40 ASA physical status I–II male patients from 20- 60 years old scheduled for elective inguinal hernia repair under spinal anesthesia will be included in this randomized double-blind comparative study. They will be randomly allocated to one of two groups according to a computer generated list of 80 patients each. Group B: (n=40) patients receiving hyperbaric bupivacaine 0.5% (Marcaine, Sunny Medical, Egypt). Group P; (n=40) will receive prilocaine2% (Takipril, Sunny Medical, Egypt). Patients suffering from neurological diseases, uncompensated cardiac or respiratory problems, active

lumber disc herniation, and history of addiction to other substances as well as those under treatment affecting results will be excluded from the study. Also, patients with a history of previous back surgery, infection at the injection site, hypersensitivity to amide local anesthetics, mental disturbance, congenital or acquired methemoglobinemia, coagulation disorders will also be excluded from the study.

The ambient temperature of the operating room will be set at 22 ± 1 °C. Standard monitoring, including 5-lead ECG, NIBP, SpO2, temperature will be measured all through the procedure. Baseline hemodynamic will be recorded then an I.V. 18- gauge cannula will be inserted. Preload of 500 ml of 0.9% NaCl will be given over 15 min to both groups. All fluids will be warmed prior to infusion. Hemodynamic parameters after the preload will bemeasured before starting the procedure.

In both groups the patients will be in the sitting position after preparation and draping of the patient's back. A skin wheal will be made by 1 ml of lidocaine HCl 2% at L3-4 interspace using a 25-gauge needle. Hyperbaric bupivacaine 0.5% will be given in dose (15mg) in group B and hyperbaric prilocaine2% in dose (60mg) in Group P. Anesthesia will be prepared by personnel not involved in this study. Patients will be supplemented with oxygen 5.0 l/minute by face mask.

Time to achieve T10 dermatome will be recorded also motor level by modified Bromage motor blockade score; 4=no motor block, 3=can flex leg at knee, 2=can flex leg at the ankle and 1= complete motor block. The time needed to reach the maximum block will be recorded. In both groups the hemodynamic parameters will be recorded before block, immediately after block then every 5 min till end of the operation. Need for sedation or analgesia will be recorded. At the end of the operation shivering and gradingits severity using Bedside Shivering Assessment Score (BSAS) will be recorded as, grade 0 if there is no shivering, grade 1 if there is no muscle contraction but mild fasciculation of face or neck or peripheral vasoconstriction but no visible shivering, grade 2 if there is a visible

muscular activity in only one muscle group, grade 3 if the muscular activity is in more than one muscle group but not generalized and grade 4 if gross muscular activity involving the entire body (13-14.) for 60 minutes postoperatively.

Once the patients have shivering, the anesthesiologist will administer pethidine 0.5 mg/kg and the time that elapsed from commencement of the treatment to the cessation of shivering will be measured.

Visual Analog Scale (VAS) and quantitative pain measurement willbe done in the immediate postoperative period and over 60 minutes postoperatively. VAS graduated from 0 (no pain) to 10 (worst imaginable pain) will be used. Side effects, such as pruritus, hypotension (a fall in systolic blood pressure > 20% from baseline) will be managed by5mg ephedrine bolus, bradycardia (< 45 beats/minute) will be treated by 0.01mg/kg atropine, nausea and vomiting will be treated by 0.2mg/kg metoclopramide. All side effects and their treatment will be recorded. The patient and the observers collecting data will be blinded to the patient's study group allocation.

Statistical analysis

Using the PASS 15 program for sample size calculation , after reviewing results from the previous relavant study (fayed et al.2024) [12] we assume an effect size difference (d=0.7) regarding the mean Bedside Shivering Assessment Score (BSAS) between the two groups , based on this assumption and after 10 % adjustment for dropout rate a sample size of at least 40 patients per group achieve 80 % power to reject the null hypothesis of zero effect size when the population effect size 0.70 and the significance level (alpha) is 0.050 using a two-sided two-sampled equal-variance t-test.

Statistical analysis will be performed using Statistical Package for Social Sciences (SPSS) version 19 computer program. Parametric data will be analyzed using one-way analysis of variance. Non-parametric data will be analyzed by using the chi-square test. A p-value of < 0.05 will be considered to be statistically significant.

References:

1. Fitzgibbons RJ, Forse RA (2015) Clinical practice. Groin hernias in adults. The New England Journal of Medicine 372(8): 756-763.
2. Sessler DI. Perioperative thermoregulation and heat balance. Lancet 2016 25;387(10038):2655-2664. Review
3. Maria Bermudez Lopez et al, Postanaesthetic shivering – from pathophysiology to prevention Romanian Journal of Anaesthesia and Intensive Care 2018 Vol 25 No 1, 73-81 DOI: http://dx.doi.org/10.21454/rjaic.7518.251.xum
4. Asghar Karbord, Hamid Kayalha, Mohammad Qasem Roushanfekr, Habibolah Mehdipoor (2019) Effectiveness Dose of Ketamine for Control of Shivering During Spinal Anesthesia in Surgeries. J Anesth Pain Med 4(4): 1-5.
5. Zhang J, Poucke SV. Dexmedetomidine as a neuraxial adjuvant for prevention of perioperative shivering: meta-analysis of randomized controlled trials. PLoS One. 2017;12(8):e0183154. doi:10.1371/journal.pone.0183154
6. Uk NGA. Prevention and Management of Hypothermia and Shivering; 2021.
7. Luggya TS, Kabuye RN, Mijumbi C, et al. Prevalence, associated factors and treatment of post spinal shivering in a Sub-Saharan tertiary hospital: a prospective observational study. BMC Anesthesiol. 2016;16(1):1–5. doi:10.1186/s12871-016-0268-0
8. Botros JM, Mahmoud AMS, Ragab SG, et al. Comparative study between Dexmedetomidine and Ondansetron for prevention of post spinal shivering. A randomized controlled trial. BMC Anesthesiol. 2018;18(1):1–8. doi:10.1186/s12871-018-0640-3
9. BECKER D.E. and REED K.L.: Local anesthetics: A review of pharmacological considerations. Anesth. Prog., 59 (2): p.90-102. DOI: 10.2344/0003-3006-59.2.90. | Open in Reading by QxMD, 2012.
10. Andlauer J, Ngatcha R, Gouwy J et al. (2019): ESRA19-0189 Hyperbaric prilocaine for one-day spinal anesthesia: a large cohort retrospective study. Regional Anesthesia & Pain Medicine, 44: 160-164.
11. Vagts D, Bley C, Mutz C (2013): Use of 2% hyperbaric prilocaine for spinal anesthesia: sensitivity analysis in outpatient surgery. Der Anaesthesist, 62(4): 271-277.
12. Fayed et al. Comparative Study Between Intrathecal Hyperbaric Prilocaine Versus Hyperbaric Bupivacaine in Anorectal Surgery. Al-Azhar International Medical Journal 5 (2024) 7-e81 DOI: https://doi.org/10.58675/2682-339X.2276
13. Kamal MM, Hussein NS. Prevention of postspinal shivering by using ketamine plus midazolam in comparison with nefopam. Egypt J Anaesth. 2011;27(1):1–5. doi:10.1016/j.egja.2010.12.002
14. Elsonbaty M, Elsonbaty A, Saad D. Is this the time for Magnesium sulfate to replace Meperidine as an antishivering agent in spinal anesthesia? Egypt J Anaesth. 2013;29(3):213–217. doi:10.1016/j.egja.2013.03.002