Comparison of the analgesic efficacy of periarticular infiltration and pericapsular nerve group block for total hip arthroplasty: A Randomized, Non-Inferiority Study

Trial Protocol

The schedule of enrolments, interventions and assessments

	Pre OP day 1	Day of surgery	POD 1	POD 2
Enrollment	■			
Informed consent	■			
Allocation		■		
Intervantion		■		
QOR 40	■		■	■
Opioid consumption				■
Pain score		■	■	

Primary aims

We aim to complete a randomised control trial to test the hypothesis that the the analgesia of PENG was non-inferior to that of PAI as measured by the NRS pain score.

Secondary aims

Secondary aims are to compare the PAI and PENG on pain score during postoperative 24 hours, cumulative opioid consumptions by PCA device, quality of postoperative recovery score, and patient satisfaction.

Study design

This is a single center prospective, single-blind randomised controlled clinical trial. Recruitment wiil be commenced on May 2020, and total recruitment is expected to take 12 months.

Randomisation and blinding

Patients will be randomised to one of the trial groups using at a ratio of 1:1 using a computer-generated table of random numbers with 2 and 4 block sizes. To conceal the allocation, the table will be uploaded to the REDCap software in our institution and will be accessible only to the researcher who prepared the study drug. After arrival of operation room, group allocation will be performed by single researcher. The attending anaesthesiologist will not be blinded to the group allocation.

Recruitment

Potential participants will be screened by the surgical and anesthetic teams who will then inform a member of the research team of the potential availability of the patient for the trial. A member of the research team will then approach the patient, confirm the initial screening for suitability and then obtain informed consent for study participation if the patient wishes to be involved in the study. Participants will be informed that their participation in the study is entirely voluntary and they are free to withdraw from the study at any time and this will have no bearing on the quality of care they receive. Patients who are unable to give informed consent due to cognitive impairment will be excluded from the trial. Active participation in the study will be until 2 days postoperatively. At 24 h and 48 h, patients will be asked to complete the QoR-40 questionnaire.

Inclusion criteria

Male and female aged >40 ,<80

Able to provide written informed consent

ASA grade I–III

Exclusion criteria

Refusal to participate in this study, hypersensitivity or allergies to local anesthetics or morphine, and contraindications to neuraxial block.

Standard spinal Anesthesia

Spinal anesthesia will be identical in both groups. The patients will be received intramuscular 2 mg of midazolam as premedication 30 min before surgery. Spinal anesthesia will be performed with standardized monitoring. 10 to 12 mg of 0.5% heavy bupivacaine with 100 μg of morphine will be titrated according to patient height and will be injected with a 25-gauge spinal needle at the L4-5 or L5-S1 level to achieve sensory block of the T8-10 dermatome.

Study intervention

The PENG block will be performed with the patient in the supine position. A linear high-frequency ultrasound probe (HFL50xp: 15–6 MHz, X-Porte) are initially placed in a transverse plane over the anterior inferior iliac spine (AIIS); the probe was turned slightly medial until the hyperechoic continuous shadow of the iliopubic eminence (IPE). The target are the plane between the psoas tendon and pubic ramus. A 22-gauge, 100 mm echogenic needle (SonoPlex cannulas, Pajunk®, Geisingen, Germany) are inserted in an in-plane approach to place the tip in the musculofascial plane between the psoas tendon anteriorly and the pubic ramus posteriorly. Following negative aspiration, 30 mL of the local anesthetic solution (0.5% ropivacaine) are injected in 5 ml increments while observing for adequate fluid spread in this plane.

Patients in the PAI group will be received intraoperative periarticular infiltration with a mixture of ropivacaine, ketorolac, epinephrine, and normal saline. Ropivacaine (0.75% ropivacaine [20 mL], ketorolac [60 mg], and epinephrine [1 g] were mixed with normal saline (total volume 100 mL) and are divided into two 50 mL-syringes. First, approximately 25 mL of the mixture are injected into the subcutaneous tissue and hip abductor muscles before skin incision through a 23-G spinal needle. Second, approximately 25 mL of the mixture are injected into the short external rotator muscles and posterior capsule before capsulotomy. Then, 5 mL of the mixture are injected into the acetabular fossa prior to insertion of the acetabular cup implants. The remaining mixture are injected into the anterior capsule and soft tissues before insertion of the femoral stem.

Outcome measures

The pain score will be assessed using the NRS (0 = no pain, 10 = maximum pain imaginable), and nausea and vomiting were assessed by yes or no questions to participants. Further, the use of additional analgesics or the incidence of other adverse effects, such as sweating, dizziness, pruritus, urticaria, and tachycardia, will be checked in the nursing records. Hypotension is defined as a systolic blood pressure less than 90 mmHg. The PCA device will be collected, and the log records will be stored in a research computer for evaluation of usage time, bolus frequency, and PCA discontinuation. Patient satisfaction will be evaluated using a 5-point Likert scale (1 = very dissatisfied, 2 = dissatisfied, 3 = neutral, 4 = satisfied, and 5 = very satisfied). The quality of postoperative recovery will be assessed using the validated Korean version of the Quality of Recovery-40 (QoR-40) questionnaire, which assesses five dimensions of recovery:physical comfort (12 items), emotional state (9 items), physical independence (5 items), psychological support (7 items), and pain (7 items). Each item are rated on a 5-point Likert scale: 1 (none of the time), 2 (some of the time), 3 (usually), 4 (most of the time), or 5 (all of the time). The total score ranged from 40 (poorest quality of recovery) to 200 (best quality of recovery). An assistant researcher administer the QoR-40 three times: the day before surgery and on postoperative day (POD) 1 and POD 2.

Statistical considerations

Data will be inspected and tested for distribution according to the Shapiro–Wilk test. Normally distributed data will be compared between study arms using the unpaired t test, whereas non-normally distributed data will be compared using the Mann-Whitney U test. All data will be summarised as mean + SD or median (25–75% range) as appropriate. Categorical variables will be reported as number (%) and analyzed using $\chi 2$ or Fisher's exact test (expected count < 5). Statistical significance are set at a two-tailed p-value of < 0.05. All statistical analyses will be performed using R software (version 4.0.3; R Project for Statistical Computing, Vienna, Austria).

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