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Optimal dose of oxycodone combined with dexmedetomidine for analgesia

Submission date 21/05/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 03/06/2026	**Overall study status** Completed	
Last Edited 28/05/2026	**Condition category** Surgery	

Plain English summary of protocol
Objective: Evidence on optimal oxycodone dosing with dexmedetomidine for patients aged ≥75 years undergoing percutaneous kyphoplasty (PKP) is lacking. This randomized, double-blind trial compared three oxycodone doses (0.03, 0.05, 0.07 mg/kg) to identify the optimal analgesic ceiling.
Methods: 150 patients (≥75 years, American Society of Anesthesiologists (ASA) II–III) were randomized into three groups (n=50 each) to receive intravenous oxycodone at 0.03 (L), 0.05 (M), or 0.07 (H) mg/kg, plus dexmedetomidine (0.5 μg/kg loading, 0.2 μg/kg/h maintenance). Primary outcome: Numerical Rating Scale (NRS) pain scores at five perioperative time points. Secondary outcomes: hemodynamics, bispectral index (BIS), Modified Observer's Assessment of Alertness /Sedation (MOAA/S), adverse events, and patient/surgeon satisfaction.
Results: At T2 (trocar insertion), M and H had lower NRS than L (P<0.05), with no difference between M and H. At T3, H was lower than L (P<0.05), but M vs. L showed no difference. MOAA/S was lowest in H (P<0.0001), but all groups had median 4 (arousable sedation). Respiratory depression was higher in H (14.0%) than L (2.0%) and M (4.0%) (P=0.033). PONV was numerically highest in H (12.0% vs. 4.0% and 6.0%, P>0.05). Group M achieved the highest patient and surgeon satisfaction (P<0.05).
Conclusion: Oxycodone 0.05 mg/kg combined with dexmedetomidine provides maximal pain relief and satisfaction with a favorable safety profile, representing the optimal analgesic ceiling for PKP in patients aged ≥75 years.

Contact information

Type(s)
Scientific, Public, Principal investigator

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Study information

Scientific Title
Optimal dose of oxycodone combined with dexmedetomidine for analgesia in septuagenarians undergoing percutaneous kyphoplasty: a randomized controlled trial

Study objectives
Evidence on optimal oxycodone dosing with dexmedetomidine for patients aged ≥75 years undergoing percutaneous kyphoplasty (PKP) is lacking. This randomized, double-blind trial compared three oxycodone doses (0.03, 0.05, 0.07 mg/kg) to identify the optimal analgesic ceiling.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/06/2022, Medical Ethics Committee of Beijing Chuiyangliu Hospital (No. 2, Chiyangliu South Street, Chaoyang District, Beijing, 100022, China; +86 (0)15110224068; cylkj@bjchy.gov.cn), ref: 2022-009KY

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Dose comparison

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Percutaneous kyphoplasty (PKP)

Interventions
Eligible patients were randomly assigned to one of three groups (L, M and H) in a 1:1:1 ratio. A computer-generated randomization sequence was created by an independent statistician using SPSS version 26.0 (IBM Corp., Armonk, NY, USA) with random block sizes of 6 to ensure balance.

Upon arrival in the operating room, all patients received supplemental oxygen via a face mask (flow rate: 3 l/min). Peripheral venous access was established, and continuous monitoring was initiated, including electrocardiography (ECG), non-invasive blood pressure (BP), pulse oxygen saturation (SpO_2), and the bispectral index (BIS). Following a 5-minute quiet rest period, baseline BP and heart rate (HR) were calculated as the mean of two consecutive measurements at 2-minute intervals and recorded as the baseline values at T0. A loading dose of dexmedetomidine (0.2 μg/kg) was administered intravenously to all patients over a 15-minute period. Given the relatively short duration of the procedure, no continuous maintenance infusion was employed. Patients were subsequently assisted into the prone position. During skin disinfection, patients in Groups L, M, and H received slow intravenous injections of oxycodone at doses of 0.03, 0.05, and 0.07 mg/kg, respectively, with an injection duration of no less than 2 minutes. Local infiltration anesthesia was performed by the surgeon using 20–30 ml of 1% lidocaine, targeting the extra-pedicular area of the corresponding segments with layer-by-layer infiltration from the skin to the vertebral periosteum.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Oxycodone

Primary outcome(s)
1. Pain intensity measured using the Numeric Rating Scale (NRS) at upon entering the operating room (T0), during local anesthesia infiltration (T1), during trocar insertion (T2), during bone cement injection (T3), and at the completion of the surgery (T4)

Key secondary outcome(s)

Completion date
01/01/2025

Eligibility

Key inclusion criteria
1. Age ≥75 years
2. Confirmed diagnosis of osteoporotic vertebral compression fracture (OVCF) by imaging (X-ray, CT, or MRI)
3. Elective single-segment PKP surgery indicated
4. American Society of Anesthesiologists (ASA) physical status II–III
5. Voluntary written informed consent obtained from the patient or a legal proxy

Healthy volunteers allowed

No

Age group
Senior

Lower age limit
75 Years

Upper age limit
95 Years

Sex
All

Total final enrolment
150

Key exclusion criteria
1. Severe cardiac or cerebrovascular diseases
2. Significant hepatic or renal impairment (defined as Child-Pugh class C or a glomerular filtration rate <30 ml/min/1.73 m^2)
3. A history of chronic pain or opioid dependence
4. Known hypersensitivity to the study medications

Date of first enrolment
01/01/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
China

Sponsor information

Organisation
Beijing Chuiyangliu Hospital

ROR
https://ror.org/04ky9n739

Funder(s)

Funder type

Funder Name
Enze Pain Management Medical Research Project of Bethune Charity Foundation (ezmr2022-062)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available