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ADMINISTRATIVE INFORMATION

Support - None reported.

Review Stage at time of this submission - Formal screening of search results against eligibility criteria.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202360076

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 June 2023 and was last updated on 26 June 2023.

INTRODUCTION

Review question / Objective The aim of this meta-analysis of randomized controlled trials was to assess the effectiveness and safety of ketorolac as an adjunct to the treatment of postoperative pain symptoms in adults undergoing orthopedic surgery.

Condition being studied Pain, the fifth most important vital sign, is a complex subjective sensation that is closely related to the onset, progression, and regression of disease. Persistent pain after orthopedic surgery not only leads to negative physiological and psychological effects on the patient but can even develop into uncontrollable chronic pain and reduce the quality of life. Therefore, how to effectively, economically, and safely reduce pain in post-operative orthopedic patients has been the focus of clinical

attention. NSAIDs are gradually being widely used in clinical medicine due to their antipyretic, anti-inflammatory, and analgesic properties. The side effects cannot be ignored and their effectiveness and safety are yet to be evaluated.

METHODS

Participant or population We included randomized controlled trials comparing Ketorolac with a placebo or another active treatment in the treatment of postoperative pain in participants aged 14 years and older (including 14 years) following orthopedic surgery.

Intervention Ketorolac use was the main intervention.

Comparator Those using non-ketorolac NSAIDs, opioids or other active treatment measures were used as comparative intervention controls.

Study designs to be included We included randomized controlled trials (RCTs) assessing the analgesic effect of enteral or parenteral ketorolac for post-operative orthopedic pain procedures. We requested full-text journal publications, online clinical trial results, abstracts of other unpublished clinical trials, and abstracts with sufficient data for analysis. We excluded short abstracts (usually conference reports). We included both blinded and unblinded trials.

Eligibility criteria We included any study that reported any of the following outcome indicators. We included studies of subjects' self-reported pain relief or pain intensity, or clinicians' assessment of pain using validated behavioural scales.

Information sources MEDLINE Ovid, Pubmed, Embase Ovid.

Main outcome(s) We anticipated that studies would use a variety of outcome measures for pain intensity, based on participant age, development, and ability to participate. We expected that most outcomes would use standard subjective scales, both self-report measures (Poker Chip Tool, Faces Pain Scale-Revised, Visual Analogue Scale (VAS)) and observational measures (Faces, Legs, Arms, Cry, Consolability (FLACC), COMFORT Scale, as recommended by PedIMMPACT (McGrath 2008).

Quality assessment / Risk of bias analysis We performed the following assessments for each of the included studies. Random sequence generation (to check for possible selection bias). Allocation concealment (to check for possible selection bias). Blinding for outcome assessment (to check for possible assay bias). Incomplete outcome data (examining possible missing visit bias due to volume, nature and treatment of incomplete outcome data). Selective reporting (check for reporting bias). Study size (to check for possible confounding bias due to small size). We intend to use a method designed to detect volume to assess publication bias Unpublished data are needed to make any results clinically irrelevant. We will use the GRADE system to assess the overall quality of the evidence for each outcome.

Strategy of data synthesis We performed all meta-analyses in duplicate using RevMan 5. We reported summary statistics, including summary RRs and MDs with 95% confidence intervals (CIs)

using RevMan 5. We considered a RR with the range of the lower and upper bounds of the 95% CI not crossing one as statistically significant, and MDs with the range of the lower and upper bounds of the 95% CIs not crossing zero as statistically significant. We used a fixed-effect model.

Subgroup analysis We intend to perform subgroup analyses to assess clinical effect heterogeneity by calculating RR or MD and the corresponding CI for each subgroup. We intend to use the Chi² test for fixed effects heterogeneity to compare subgroups. We consider that non-overlapping confidence intervals are associated with the difference.

Sensitivity analysis We intend to conduct sensitivity analyses by removing studies with non-self-reported pain scores. However, inadequate sensitivity data analysis was necessary.

Country(ies) involved China.

Keywords Ketorolac, Non-steroidal anti-inflammatory drugs, Adults, Post-operative analgesia, meta-analysis.

Contributions of each author

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