INPLASY PROTOCOL

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None declared.

Efficacy and safety of tapentadol in knee osteoarthritis and low back pain: systematic review and meta-analysis

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Review question / Objective: **This meta-analysis aimed to evaluate the efficacy and safety of tapentadol for knee osteoarthritis pain and low back pain. 1. Patients: Patients diagnosed with KOA according to the American College of Rheumatology criteria. Patients with low back pain had been diagnosed with low back pain for ≥ 3 months prior to enrollment. All patients were aged ≥ 18 years, regardless of male or female patients. 2. Intervention: The interventions in the experimental group were patients treated with oral tapentadol for knee osteoarthritis pain and low back pain, with tapentadol oral doses ranging from 50 mg to 600 mg. 3. comparison intervention: The intervention in the control group was the administration of different painkillers (e.g., oxycodone, etoricoxib), or placebo as the intervention. 4. report at least one of the following outcomes: (a) For the primary efficacy outcome measure, we assessed control of pain by changes in pain intensity scores. Among them, scales assessing the primary efficacy outcome measure (11-point numerical rating scale (NRS)) are included, (b) patient global impression of change (PGIC)(17), (c) AEs, (d) discontinuations due to adverse events.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 December 2022 and was last updated on 08 December 2022 (registration number INPLASY2022120032).

INTRODUCTION

Review question / Objective: **This meta-analysis aimed to evaluate the efficacy and safety of tapentadol for knee osteoarthritis pain and low back pain. 1. Patients: Patients diagnosed with KOA according to the American College of Rheumatology criteria. Patients with low back pain had been diagnosed with low back pain for ≥ 3 months prior to enrollment. All patients were aged ≥ 18 years, regardless of male or female patients. 2. Intervention: The interventions in the experimental group**

were patients treated with oral tapentadol for knee osteoarthritis pain and low back pain, with tapentadol oral doses ranging from 50 mg to 600 mg. 3. comparison intervention: The intervention in the control group was the administration of different painkillers (e.g., oxycodone, etoricoxib), or placebo as the intervention. 4. report at least one of the following outcomes: (a) For the primary efficacy outcome measure, we assessed control of pain by changes in pain intensity scores. Among them, scales assessing the primary efficacy outcome measure (11-point numerical rating scale (NRS)) are included, (b) patient global impression of change (PGIC)(17), (c) AEs, (d) discontinuations due to adverse events.

Condition being studied: Osteoarthritis is the most common disease, affecting more than 500 million people worldwide. Among them, more than 260 million people suffered from knee arthritis, an increase of 9.3% from 1990 to 2017. Low back pain has become a common symptom in people of all ages. In 2015, the global prevalence of activity-limiting low back pain was 7.3%; Low back pain is now the leading cause of disability worldwide. The current study demonstrates that tapentadol is effective in relieving knee osteoarthritis pain and low back pain. Therefore, the efficacy and safety of tapentadol for the treatment of knee osteoarthritis pain and low back pain were assessed by a meta-analysis.

METHODS

Participant or population: Patients diagnosed with KOA according to the American College of Rheumatology criteria. Patients with low back pain had been diagnosed with low back pain for ≥ 3 months prior to enrollment. All patients were aged ≥ 18 years, regardless of male or female patients.

Intervention: The interventions in the experimental group were patients treated with oral tapentadol for knee osteoarthritis pain and low back pain, with tapentadol oral doses ranging from 50 mg to 600 mg.

Comparator: Placebo, no treatment or another active treatment (e.g. Non-steroidal anti-inflammatory drugs or Physiotherapy).The intervention in the control group was the administration of different painkillers (e.g., oxycodone, etoricoxib), or placebo as the intervention.

Study designs to be included: Randomized controlled trials(RCTs).

Eligibility criteria: Patients diagnosed with KOA according to the American College of Rheumatology criteria. Patients with low back pain had been diagnosed with low back pain for ≥ 3 months prior to enrollment. All patients were aged ≥ 18 years, regardless of male or female patients.

Information sources: We will conduct a search and obtain the literature from the Cochrane Central Register of controlled trials (central), PubMed, EMBASE, web of science.

Main outcome(s): The 11-point numerical rating scale (NRS) was adopted to assess the change in patients' pain intensity was the primary outcome measure in our inclusion.

Quality assessment / Risk of bias analysis: Cochrane Collaboration's risk of bias tools.

Strategy of data synthesis: We will employ a random effects model to estimate the pooled results. For dichotomous outcomes, we calculated relative risks (RRs) and 95% confidence intervals (CIS). For continuous variables, we calculated the standard mean difference (SMD) and its 95% CI for estimating the effect size. Heterogeneity between studies was assessed using the Q test and the I2 statistic. I2 > 50% and P < 0.1 were considered significant heterogeneity. To explore possible sources of heterogeneity.

Subgroup analysis: Our study included patients with knee osteoarthritis pain and low back pain. We will perform a subgroup analysis on the etiology of pain and the duration of follow-up.

Sensitivity analysis: If sufficient studies are available, we will conduct sensitivity analyses based on the quality of the methods, sample size, and choice of missing data to test the robustness of the studies.

Country(ies) involved: China.

Keywords: Osteoarthritis; Low back pain; Tapentadol; Meta-analysis.

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