

Safety and Efficacy of Tapentadol in Osteoarthritis: A Prospective Observational Study.

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ABSTRACT

Background: Osteoarthritis (OA) is the most common type of arthritis. Its high prevalence, especially in the elderly, and the high rate of disability related to disease make it a leading cause of impaired mobility in the elderly. To evaluate the efficacy, safety and tolerability of tapentadol in OA of knee joint in Indian population this study was undertaken. **Methods:** A prospective observational study involving patients of 40 years and above suffering from moderate to severe pain due to OA of knee joints attending the orthopaedics OPD of the National Medical College were recruited according to inclusion and exclusion criteria. Pain intensity was measured by 10 point VAS score on baseline and 2 follow up visits at 1st and 2nd week. Patients were given 50 -100 mg twice daily oral tapentadol tablets. ADRs were noted and data analysis done. **Results:** Total of 84 with baseline mean VAS score was 4.7 (SD 0.62). Significant reductions from baseline were noted at 1 week and 2 weeks follow up visits. At first follow up visit i.e on week 1 the mean pain intensity score was 2.48 (SD 1.45) whereas in 2nd follow up visit on week 2 it was 1.7 (SD 1.39). The change in pain intensity score were statistically significant ($p < 0.0001$) for both the situations. Adverse drug events were mostly non serious. Commonly presented ADRs were diarrhoea, nausea, dizziness, constipation and hyperhidrosis. The incidence were around 6%. **Conclusion:** This observational study of pain relief in patients suffering from moderate to severe pain due to OA had been treated with tapentadol showed significant clinical improvement with few adverse effects. There are limitations due to small sample size and non-comparative design.

Keywords: Knee joint, Osteoarthritis, Tapentadol.

INTRODUCTION

Osteoarthritis (OA) is the most common type of arthritis. Its high prevalence, especially in the elderly, and the high rate of disability related to disease make it a leading cause of impaired mobility in the elderly. Because of the aging and obesity, a major risk factor, there is increase in prevalence and occurrence of OA. There are various analgesics available for management of pain associated with OA belonging to the class of either Non-Steroidal Anti Inflammatory Drugs (NSAIDs) or Opioids – natural or synthetic. Each has got its own drawbacks when used for prolonged periods of time.

Tapentadol hydrochloride is a centrally acting oral analgesic approved by the US FDA for the treatment of moderate to severe acute pain. It has a potency between morphine and tramadol. It has a unique dual mode of action as an agonist at the μ -opioid receptor and as a norepinephrine reuptake inhibitor¹. It has demonstrated efficacy comparable to classical strong

opioids like oxycodone and an improved tolerability profile in regards to the gastro intestinal side effects like nausea, vomiting and constipation. Some studies done abroad have demonstrated its better efficacy and tolerability in case of postoperative pain, chronic low back pain and OA. Therefore it was felt necessary to generate data based on Indian population.

Objective

To evaluate the efficacy, safety and tolerability of tapentadol in OA of knee joint in Indian population.

MATERIALS AND METHODS

A prospective observational study was undertaken by the department of Pharmacology and Orthopaedics in Calcutta National Medical College, Kolkata for a period of six months from November 2011 to April 2012. Necessary clearance was obtained from the Ethical-cum-Screening subcommittee of the Calcutta National Medical College, Kolkata. Both male and female patients of 40 years and above of age suffering from moderate to severe chronic knee pain due to OA and attending the Orthopedics Out Patients Department (OPD) were included. Pregnant and lactating mothers were

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excluded. Patients suffering for uncontrolled hypertension, moderate to severe renal and hepatic impairment, history of seizure or epilepsy on any other severe systemic diseases were excluded. Informed consent were obtained before participation of the study.

Ten point Visual Analog Scale (VAS) was used to document the pain. The baseline pain was recorded on first visit. According to pain intensity and body weight tapentadol was prescribed 50 mg to 100 mg twice daily. The patients were followed up in two visits 7 days apart regarding change of VAS score and any adverse events noted as well as tolerability. Data obtained were noted in excel sheet and analysed by descriptive statistical analysis.

RESULTS

A total of 90 patients were recruited after screening 110 patients attending the OPD fulfilling the inclusion and exclusion criteria and those giving informed consent for participating the study. Of these 90 patients 84 patients completed the study with all three visits, whereas 6 patients were lost to follow-up.

The mean age of the patients were 64.3 years and male were 37 whereas female were 47 out of 84 cases

The mean pain intensity score on VAS scale was 4.7 (SD 0.62). Significant reductions from baseline were noted at 1 week and 2 weeks follow up visits. At first follow up visit i.e on week 1 the mean pain intensity score was 2.48 (SD 1.45) whereas in 2nd follow up visit on week 2 it was 1.7 (SD 1.39). The change in pain intensity score were statistically significant ($p < 0.0001$) for both the situations.

Adverse drug events were mostly non serious. Commonly presented ADRs were diarrhoea, nausea, dizziness, constipation and hyperhidrosis. The incidence were around 6%. Two cases of abdominal pain and dysphagia were noted. But by physical examination or laboratory values showed no significant and relevant changes.

DISCUSSION

The patients included in the present study were suffering from moderate to severe pain due OA. There was a need of strong analgesic either NSAIDS or opioids. Here overall therapy with tapentadol was quite effective for relief of pain. In different regulatory guidelines OA pain were regarded as a model of nociceptive pain.^[1-4,8] But the association of pain due to underlying pathology like cartilage damage, chronicity of pain need to considered in choosing therapy.^[1] The descending inhibitory pathway can modulate this pain sensation. Duloxetine therapy is employed targeting this pain modulatory pathway in OA. Continuing mechanical damage and tissue degradation which is associated

with OA being mediated through ascending pathway, opioids target this pathway of pain.^[9] Here lies the importance of combining an action of opioid with the action due to noradrenergic mechanism to control moderate to severe pain associated with OA. So tapentadol may be useful for this condition.

Overall the incidence of ADRs were consistent with what has been observed in other placebo controlled trials.^[5,6] Significant improvement in pain occurred in some similar studies.^[7]

CONCLUSION

This observational study of pain relief in patients suffering from moderate to severe pain due to OA had been treated with tapentadol showed significant clinical improvement with few adverse effects. There are limitations due to small sample size and non-comparative design.

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