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A Clinical study on Management of Osteoarthritis

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ABSTRACT
The primary symptoms are pain and stiffness of the affected joints, secondarily leading to joint dysfunction, deformities, and muscular weakness. It is the most common form of arthritis with approximately 250 million people worldwide conservatively estimated to be suffering from osteoarthritis of the knee alone. We, therefore, thought it worthwhile to compare the efficacy and tolerability of oxaceprol, in comparison to the relatively weak opioid tramadol, in the treatment of symptomatic knee osteoarthritis. The study protocol was approved from institutional ethical committee. All patients were informed regarding the study and written consent was obtained. General information such as name, age, gender etc. was recorded. A careful examination was done in all patients. Patients were divided into 2 groups. Group I received oxaceprol 200 mg capsule and group II or tramadol 50 mg capsule, thrice daily for 12 weeks. Patients were recalled regularly. Mean WOMAC score pain in group I was 258 which decreased to 228 in group I and 253 which decreased to 203 in group II. The difference was significant ($p<0.05$). WOMAC stiffness score in group I was 27.1 which decreased to 21 in group I and 29.2 which decreased to 23.3 in group II. WOMAC physical function score in group I was 916 which decreased to 728 in group I and 892 which decreased to 780 in group II. The difference was significant ($p<0.05$). Both drugs found to be equally effective in management of cases.

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Key Words
Oxaceprol, tramadol, osteoarthritis

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INTRODUCTION

Joint pain and stiffness are the main symptoms, which are followed by deformities, weakness in the muscles and joint dysfunction. It is the most prevalent type of arthritis; the conservative estimate puts the number of people with osteoarthritis of the knee alone at 250 million worldwide[1].

The primary symptom of osteoarthritis (OA) patients is pain, which has a major influence on functional ability, severely limits daily living activities, and is linked to a large loss of productivity and a reduced quality of life. Known as an age-related condition, it most commonly affects joints that have seen constant tension over time, such as the lower back, hips, knees and minor joints in the hands[2]. Using analgesics first paracetamol, then non-steroidal anti-inflammatory drugs (NSAIDs), less potent opioids like tramadol, and finally potent opioids like oxycodone or hydromorphone to treat pain symptomatically is the main focus of the traditional pharmacological approach[3]. Degenerative joint disease has been treated with oxaceprol, a hydroxyproline derivative ([4R] 1 acetyl 4 hydroxy L proline).

It is thought to be the fourth most common cause of disability in Asia[4.5]. In Indian cities the prevalence of osteoarthritis is approximately 4% but in rural regions, it is 6%.6, 7 Osteoarthritis, once believed to be a typical side effect of ageing, is now understood to be the result of a complex interaction between several additional factors, including genetic predisposition, mechanical stresses, local inflammation and cellular and metabolic processes[6-8].

As of right now, there are no clinically validated treatments to stop the start or progression of osteoarthritis. Using analgesics first paracetamol, then nonsteroidal anti-inflammatory drugs (NSAIDs), less potent opioids like tramadol and finally potent opioids like oxycodone or hydromorphone to treat pain symptomatically is the main focus of the traditional pharmacological approach. Other therapies include intra-articular corticosteroid and sodium hyaluronate injections, topical administration of diclofenac or capsaicin and controversial intra-articular hyaluronic acid injections into the affected knee joint[9]. Depending on the affected joints and the patient's lifestyle, surgical techniques including osteotomy, resurfacing, or joint replacement may be taken into consideration if the symptoms of osteoarthritis significantly impair quality of life and conservative therapy is ineffectual.

India has recently been exposed to oxaceprol. For this reason, we believed it was important to evaluate the effectiveness and tolerability of oxaceprol vs the somewhat ineffective opioid tramadol while treating symptomatic osteoarthritis in the knee.

MATERIALS and METHODS

It comprised of 128 cases of OA of both genders. The study protocol was approved from institutional ethical committee. All patients were informed regarding the study and written consent was obtained.

General information such as name, age, gender etc. was recorded. A careful examination was done in all patients. Patients were divided into 2 groups. Group I received oxaceprol 200 mg capsule and group II or tramadol 50 mg capsule, thrice daily for 12 weeks. Patients were recalled regularly. In all patients, pain, stiffness and physical function, measured on 100 mm VAS scale was recorded. Results were subjected to statistical analysis. $p>0.05$ was considered significant.

RESULTS

Table 1 shows that out of 108 patients, males were 68 and females were 40. Table 2 shows that both groups had 54 patients.

Table 3 shows that mean WOMAC score pain in group I was 258 which decreased to 228 in group I and 253 which decreased to 203 in group II. The difference was significant ($p<0.05$). WOMAC stiffness score in group I was 27.1 which decreased to 21 in group I and 29.2 which decreased to 23.3 in group II. WOMAC physical function score in group I was 916 which decreased to 728 in group I and 892 which decreased to 780 in group II. The difference was significant ($p<0.05$).

DISCUSSIONS

Depending on the affected joints and the patient's lifestyle, surgical techniques including osteotomy, resurfacing, or joint replacement may be taken into consideration if the symptoms of osteoarthritis significantly impair quality of life and conservative therapy is ineffectual. But since osteoarthritis is a common condition and joint replacement surgery is a last resort offered by a small number of specialised facilities, the search for novel osteoarthritis medications must go on. Ten There is yet no truly disease-modifying anti-osteoarthritis medication on the market. In this study the therapy of OA cases was examined between tramadol and oxaceprol.

Of the 108 patients in this study, 68 were male and 40 were female. There were 54 patients in each group. According to the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) version 3.1, which measures pain, stiffness and physical function,

Table 1: Distribution of patients

	Total-128	
Gender	Male	Female
Number	78	50

Table 2: Distribution of patients in groups

Groups	Group I (oxaceprol)	Group II (tramadol)
Number	64	64

Table 3: Western ontario and mcMaster universities osteoarthritis Index score changes in both groups

Parameters	Groups	Preoperatively	After 12 weeks	p-value
WOMAC pain	Group I	258	228	0.05
	Group II	253	203	
WOMAC stiffness	Group I	27.1	21.0	0.15
	Group II	29.2	23.3	
WOMAC physical function	Group I	916	728	0.74
	Group II	892	780	

Smith[10] discovered that the main efficacy variable was symptom alleviation. Other outcomes that were examined included the patient's Clinical Global Impression (CGI) the responder rate (50%) for pain reduction and the need of rescue medication. For the purpose of conducting a safety evaluation, vital signs, regular blood counts, hepatorenal function tests, and treatment-emergent adverse events were noted. Out of the 91 individuals that were enrolled, 36 were on tramadol and 43 were on oxaceprol. For the whole 12-week research period the WOMAC scores in each arm dramatically decreased from baseline but stayed similar between groups. At the last visit the CGI ratings and 50% responder rates were likewise similar. The amounts of rescue medication and dose up-titration varied, although not in a statistically significant way. The adverse event counts were the same. In both groups, compliance was satisfactory.

We discovered that group I's mean WOMAC score for pain was 256, this dropped to 225 in group I and group II's mean WOMAC score dropped to 201. There was a substantial difference ($p<0.05$). The WOMAC stiffness score dropped from 26.7 in group I to 21 in group I and from 28.3 to 22.1 in group II. The WOMAC physical function score dropped from 912 in group I to 725 in group I and from 890 in group II to 778 in group II. Bauer *et al*.[11,12] conducted a multicenter, randomised, double-blind research in Germany that evaluated the three-week duration of oxaceprol (200 mg) and diclofenac (25 mg) treatments. Clinical improvements were seen in joint function, as measured by Lequesne's indices, in both therapy groups. The pain-free walking period more than doubled, joint mobility increased by almost 60% and the VAS score for pain decreased by over 50% in both groups. Group differences were not statistically significant. Except for oxaceprol the incidence of ADRs was comparable in the two groups.

There are some limitations to the current investigation. Even though the 12 week research period was longer than previous studies, osteoarthritis is a chronic condition and it is not sufficient to determine long-term safety and efficacy. We did not follow-up people for more than 12 weeks, so we are unable to comment on whether benefits will last after drug withdrawal or on the efficacy of the medication in treating advanced osteoarthritis, as these patients were excluded from the trial. It's also critical to remember that the study was designed to detect differences in the WOMAC pain score component between the groups of 30 on the VAS scale. Although it was less ambitious than the 10 mm margin utilised in that study, this margin was selected using the same guidelines as an earlier key study 13. Although differences were noted, they were not considered statistically significant because they were less than thirty. Because the study was not intended as an inferiority trial but rather as a standard study, there will be some statistical hesitancy regarding our conclusion. This study has focused on improving functional abilities and relieving symptoms rather than examining the influence on the advancement of the disease. Consequently, we did not employ any radiological disease severity grading.

CONCLUSION

Authors found that OA is common phenomenon among patients. Both drugs found to be equally effective in management of cases. Oxaceprol efficacy and tolerability was comparable with tramadol and the drug can be considered as an alternative to low-potency opioids in the management of knee osteoarthritis. Further studies are required to confirm the clinical utility of oxaceprol in osteoarthritis.

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