

Comparison Study of Therapeutic Efficacy and Safety of Aceclofenac and Tramadol in the Treatment of Osteoarthritis Patients, Bangalore, India

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Abstract

Objectives: To compare efficacy of Aceclofenac and Tramadol in the treatment of osteoarthritis patients and to evaluate safety of Aceclofenac and Tramadol in the treatment of osteoarthritis patients. **Methodology:** A hospital based prospective study to determine efficacy and safety of Aceclofenac and tramadol among osteoarthritis patients. Demographic details (Name, age and sex) of patient were collected. Admission, discharge date, diagnosis of the patient and drug data (Brand and generic name) of antihypertensive drugs (tramadol, Aceclofenac) prescribed, dose frequency, route of administration, dose were recorded. The osteoarthritis pain questionnaire was arranged to assess the state of patients with osteoarthritis, including stiffness, pain and physical functioning of the joints. The mean response of all included patients before and after receiving tramadol and Aceclofenac has been documented. Probability values (p value) less than 0.05 were considered significant. **Results:** Total 150 patients who fulfilled study criteria were included in the study. Of total patients 54 (36%) and 96 (64%) patients were male and female respectively. Most of the male patients 24 (16%) and female patients 42 (28%) were in the age group of 70-79 year. Determination of body mass index distribution among patients showed majority of patient 73 (48.67%) at obese nutritional status followed by 51 (34%) were at pre-obese nutritional and 26(17.33%) were at normal weight status. Mean \pm SD of collected response to pain questionnaire before administration of medications (tramadol and aceclofenac), at the day of admission was measured to be 113.62 ± 26.2 . the mean \pm SD of collected response to pain questionnaire after receiving tramadol was found to be 52.63 ± 22.42 and the mean \pm SD of same inquiry from was measured to be 82.25 ± 21.77 . out of total, fifty-one patients complained adverse drug reactions. In personal study we found, tramadol only contributed in only ninth number of all reported adverse effects including nausea, vomiting and fatigue, whereas aceclofenac was found to be reason for forty-two number of adverse drug containing epigastric pain, nausea, fatigue and tachycardia. **Conclusion:** in current study, we collected tramadol was more effective and safer than aceclofenac with P value: 0.0062 (probability value less than 0.05 were considered significant which showed significant result in pain-relieving effect.

Key words: Osteoarthritis, Tramadol, Aceclofenac Drug Safety and Efficacy

Introduction

Osteoarthritis (OA) has been described "as a condition described by use-related joint agony experienced on most days in some random month, for which no other reason is apparent". The pathological changes seen in OA is described by central territories of loss of articular cartilage within the synovial joints, related with hypertrophy of the bone (osteophytes and subchondral sclerosis) and thickening of the capsule (Lawrence, Felson and Helmick, 2008).

Osteoarthritis is the most common chronic musculoskeletal disorder. Epidemiological investigations gauge around 43 million influenced patients in the United States alone and about 15% of the total populace (Lawrence, Felson and Helmick, 2008; Egloff, Hügle and Valderrabano, 2012; Solignac, 2004) . It is the main source of movement constraint and non-appearance among working-age adults and is related with a critical decrease in capacity among more established people. In this conditions osteoarthritis is also a substantial economic burden, with annual medical care consideration uses of billion dollars in the United States (Kotlarz, Gunnarsson and Fang, 2009). Comprehension of changes early in the development of osteoarthritis is critical, since these progressions could in any case be reversible, and in this way, preventive treatment could be started to moderate or switch further movement of the illness.

At first, osteoarthritis has been viewed as a disease of articular cartilage, but recent examination has demonstrated that the condition includes the whole joint (Dieppe, 2011; Martel-Pelletier and Pelletier, 2010; Abramson and Attur, 2009). The loss of articular cartilage has been believed to be the essential change, but a combination of cellular changes and biomechanical stresses causes few auxiliary changes, including subchondral bone remodeling, the formation of osteophytes, the arrangement of bone marrow lesions, change in the

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synovium, joint capsule, ligaments and per articular muscles, and meniscal tears and extrusion (Goldring, 2010; Pollard, Gwilym and Carr, 2008; Dequeker and Luyten, 2008; Ding, Jones and Wluka, 2010).

The administration of osteoarthritis has moved from the customary methodology of pain control to incorporate interventions to improve resilience for functional activity and quality of life. Ideal administration includes non-drug and drug approaches that emphasis on avoiding illness and ceasing movement, as after dealing with the pain, core interventions for all patients with osteoarthritis, with or without comorbidities, are land-based exercise, weight management, strength training, water-based exercise, self-management and education (McAlindon et al., 2014). Exercise is all around prescribed by clinical guidelines, and ought to be individualized after patient evaluation. Meta-analyses have appeared exercise to have small to moderate effect sizes for improved capacity and pain relief, like those accomplished with non-steroidal anti-inflammatory drugs (NSAIDs) and analgesia (Zhang et al., 2010). Targeted muscle strengthening and general aerobic exercises are prescribed, with water-based exercises proposed for those with practical and versatility limitations (Bennell, Hunter and Hinman, 2012; Fransen and McConnell, 2009). Stretching and adaptability practices generally form part of an overall exercise program for osteoarthritis, to maintain or increment the scope of movement in the joints. Supervised group or individual exercise is superior to independent home exercise for pain reduction.6pposed to just targeting palliation of disease (Hunter, 2011).

Materials and Methods

This study was conducted on inpatients of orthopedic department of Tertiary Care Hospital, Bangalore, India. A hospital based prospective study to determine efficacy and safety of aceclofenac and tramadol among osteoarthritis patients. A total 60 patients from the orthopedic department of Tertiary Care Hospital who received aceclofenac and tramadol for management of their osteoarthritis and fulfilled the inclusion and exclusion criteria were selected for the study.

Data has been collected with respect to:

- Demographic detail: name, sex, age of patient
- Prescribed drug data: Name of drugs prescribed, dose of drugs, dose frequency, route of administration
- The osteoarthritis pain questionnaire was prepared to assess the condition of patients with osteoarthritis, including pain, stiffness, and physical functioning of the joints.
- The mean response of all included patients before and after receiving tramadol and aceclofenac has been documented.

Data were analyzed using SPSS software. Probability values (p value) less than 0.05 considered significant. Quantitative variables have been indicated in mean \pm SD. Results of continuous measurements are presented on mean \pm SD and results of categorical measurements are presented in Number, percentage (%), Microsoft word and Excel have been used to generate and tables.

Result and Discussion

A hospital based prospective study was conducted to determine efficacy and safety of tramadol and aceclofenac in management of osteoarthritis at orthopedic department of Tertiary Care Hospital, Bangalore, India. Total 150 patients who fulfilled study criteria were included in the study.

Of total patients, 54 (36%) and 96 (64%) patients were male and female respectively. it shows that in our study, the number of female patients was comparatively more than the number of male patients. Most of the male patients 24 (16%) were in the age group of 70-79 years and most of the female patients 42 (28%) were in the age group of 70-79 years. In the present study, we observed ascending trend in number of patients in relation to advancing the age.

Most studies prove a consistently strong positive association between body mass index and the risk of osteoarthritis. In present study, body mass index has been divided as per world health organization criteria into below 18.5(underweight), 18.5-24.9 (normal weight), 25.0-29.9 (pre obesity) and 30.0 or more(obese).

determination of body mass index distribution among patients showed majority of patients 73 (48.67%) at obese nutritional status followed by 51 (34%) were at pre-oboes nutritional and 26 (17.33%) were at normal weight status. Demonstrated relationship between obesity and high prevalence and severity of early degenerative changes in the knee in moderately aged people without radiographic OA and with essentially expanded cartilage lesion progression.

The majority of male patients 21 (38.98%) were suffering from neck osteoarthritis and 41 (42.71%) were diagnosed with knee osteoarthritis (Table 1)

Table 1: Osteoarthritis Joint Distribution

Osteoarthritis	Total (N = 150)		Male <N = 54)		Female (N = 96)	
	Number	%	Number	%	Number	%
Knee	60	40.00	19	35.19	41	42.71
Hip	27	18.00	6	11.11	21	21.88
Neck	30	20.00	21	38.89	9	9.38
Back	30	20.00	8	14.81	22	22.92
Shoulder	3	2.00	0	-	3	3.13

The osteoarthritis pain questionnaire was prepared and result of this inquiry form is presented at table 2. The majority of patients (98%) were suffering from pain at stair climbing followed by stiffness during day (95.33%) and weight bearing (95%), Mean \pm SD of collected response to pain questionnaire before administration of medications (tramadol and aceclofenac), at the day of admission was measured to be 113.62 ± 26.2 .

Table 2: Osteoarthritis Pain Questionnaire at Day of Admission

parameter	Chief Complaint	Number	(Percentage)%
PAIN	Walking	113	75.33
	Stair Climbing	147	98
	Nocturnal	132	88
	Rest	120	80
	Weight bearing	143	95.33
Stiffness	Morning stiffness	67	44.67
	Stiffness occurring later in the day	143	95.33
physical function	Descending stairs	120	80
	Ascending stairs	130	86.67
	Bending to floor	112	74.67
	Rising from sitting	120	80
	Standing	103	68.67
	Getting on/off toilet	67	44.67
	Getting in/out of bath	78	52
	Lying in bed	89	59.33
Rising from bed	134	89.33	
Mean \pm SD		113.62 \pm 26.2	

Response of all included patients after receiving tramadol and aceclofenac has been documented which is showed in table 3 and 4, The mean \pm SD of collected response to pain questionnaire after receiving tramadol was found to be 52.63 ± 22.42 and the mean \pm SD of same inquiry form k was measured to be 82.25 ± 21.77 .

Table 3: Osteoarthritis Pain Questionnaire after Administration of Tramadol

parameter	Chief complaint	Number	%
PAIN	Walking	78	52
	Stair Climbing	67	44.67
	Nocturnal	56	37.33
	Rest	87	58
	Weight bearing	88	58.67
Stiffness	Morning stiffness	23	15.33
	Stiffness occurring later in the day	43	28.67
physical function	Descending stairs	67	44.67
	Ascending stairs	70	46.67
	Bending to floor	45	30
	Rising from sitting	63	42
	Standing	43	28.67
	Getting on/off toilet	32	21.33
	Getting in/out of bath	24	16
	Lying in bed	23	15.33
Rising from bed	33	22	
Mean \pm SD		52.63 \pm 22.42	

Table 4: Osteoarthritis Pain Questionnaire after Administration of Aceclofenac

parameter	Chief Complaint	Number	%
PAIN	Walking	103	68.67
	Stair Climbing	101	67.33
	Nocturnal	98	65.33
	Rest	111	74
	Weight bearing	107	71.33
Stiffness	Morning stiffness	58	38.67
	Stiffness occurring later in the day	98	65.33
physical function	Descending stairs	99	66
	Ascending stairs	83	55.33
	Bending to floor	78	52
	Rising from sitting	89	59.33
	Standing	73	48.67
	Getting on/off toilet	52	34.67
	Getting in/out of bath	56	37.33
	Lying in bed	43	28.67
Rising from bed	67	44.67	
Mean ± SD		82.25± 21.77	

Table 5 shows comparison of pain-relieving effects between tramadol and aceclofenac. In current observation, we found tramadol was more effective than aceclofenac with P value: 0.0062 (Probability values less than 0.05 were considered significant) which showed significant result in pain-relieving effect (Table 5)

Table 5: Comparison of Pain-Relieving Effects between Tramadol and Aceclofenac

Mean ± SD of Pain Questionnaire		P value
Tramadol	52.63 ± 22.42	0.0062*
Aceclofenac	82.25±21.77	0.05

* Significant (p value: p < 0.01)

We observed tramadol was associated with less number of adverse drug reaction. Out of total, fifty-one patients complained adverse drugs reactions. In present study we found, tramadol only contributed in ninth number of all reported adverse effects including nausea, vomiting and fatigue, whereas aceclofenac was found to be reason for forty-two number of adverse effects containing epigastric pain, nausea, fatigue and tachycardia (Table 6).

Table 6: Comparison Number of Patients with Adverse Drug Reaction

Adverse Drug Reactions	Tramadol	Aceclofenac
Epigastric Pain	1	10
Nausea	2	14
Vomiting	2	6
Fatigue	2	8
Sleep Disorders	2	0
Tachycardia	0	4
Total	9	42

The study carried out on adverse event profile of tramadol in clinical studies of chronic osteoarthritis pain with study objective to review the safety profile of tramadol hydrochloride (tramadol) in the treatment of chronic osteoarthritis pain. The most common adverse event reported across all tramadol formulations were nausea, constipation, vomiting and headache. Most adverse events were mild to moderate in severity.

Conclusion

Osteoarthritis (OA) is a condition portrayed by central zones of loss of articular cartilage inside the synovial joints, related with hypertrophy of the bone (osteophytes and subchondral bone sclerosis) and thickening of the capsule. Osteoarthritis (OA) is the well-known type of arthritis and a major reason for pain and disability in older adults. OA is frequently alluded to as degenerative joint disease with an abnormal remodeling of joint tissues driven by a host of inflammatory mediators within the affected joint.

Complete 150 patients who satisfied investigation criteria were incorporated into the examination. The mean \pm SD of collected response to pain questionnaire after receiving tramadol was found to be 52.63 ± 22.42 and the mean \pm SD of same inquiry form was measured to be 82.25 ± 21.77 . In current study, we concluded tramadol was more effective and safer than aceclofenac with P value: 0.0062 (Probability values less than 0,05 were considered significant) which showed significant result in pain-relieving effect, out of total, fiftyone patients complained adverse drugs reactions. In present study we found, tramadol only contributed in ninth number of all reported adverse effects including nausea, vomiting and fatigue, whereas aceclofenac was found to be reason for forty-two number of adverse effects containing epigastric pain, nausea, fatigue and tachycardia.

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