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Ortholord Tablets: *Curcumin* Better Alternative in Knee Osteoarthritis Compared with Non-Steroidal Anti-Inflammatory Drugs

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ABSTRACT

Osteoarthritis is a degenerative joint disease that is the most common type of arthritis. Causes OA is caused by joint damage. This damage can accumulate over time, which is why age is one of the main causes of the joint damage leading to osteoarthritis. Osteoarthritis occurs when the cartilage that cushions the ends of bones in your joints gradually deteriorates. Cartilage is a firm, slippery tissue that enables nearly frictionless joint motion. It causes changes in the bone and deterioration of the connective tissues that hold the joint together and attach muscle to bone. The aim of the study was to determine efficacy and safety of the efficacy and safety of curcumin with those of diclofenac in the treatment of knee osteoarthritis (OA), who is intolerant to the side effects of non-steroidal anti-inflammatory drugs. A total of 80 patients were enrolled as per inclusion and exclusion criteria, patients were participated in this study, and the response was 100%. The diagnosis of Osteoarthritis in the study subjects was based on the following clinical symptoms history of Nausea, vomiting, Diarrhea, Abdominal pain, Constipation, Dyspepsia, Weakness at the first day of pharmacokinetic assessment. Curcumin has similar efficacy to diclofenac but demonstrated better tolerance among patients with knee OA. In Ortholord™ Curcumin can be an alternative treatment option in the patients with knee OA who are intolerant to the side effects of non-steroidal anti-inflammatory drugs.

Keywords: *Curcumin, Osteoarthritis, Diclofenac.*

1. Introduction

Osteoarthritis is the most common form of arthritis, affecting millions of people worldwide. It occurs when the protective cartilage that cushions the ends of your bones wears down over time. Although osteoarthritis can damage any joint, the disorder most commonly affects joints in your hands, knees, hips and spine.

Causes

Causes OA is caused by joint damage. This damage can accumulate over time, which is why age is one of the main causes of the joint damage leading to osteoarthritis. Osteoarthritis occurs when the cartilage that cushions the ends of bones in your joints gradually deteriorates. Cartilage is a firm, slippery tissue that enables nearly frictionless joint motion. It causes changes in the bone and deterioration of the connective tissues that hold the joint together and attach muscle to bone. It also causes inflammation of the joint lining.

The older you are, the more wear and tear you've had on your joints. Other causes of joint damage include past injury, such as:

(1) Torn Cartilage, (2) Dislocated Joints, (3) Ligament Injuries

Symptoms

- ✓ Stiffness
- ✓ Inflammation
- ✓ Tenderness (discomfort when pressing on the area with your fingers)

Osteoarthritis symptoms develop slowly and worsen over time. Signs and symptoms of osteoarthritis include: Pain, Stiffness, Tenderness, Loss of flexibility, range of motion, Grating sensation, Bone spurs, swelling.

2. Aim and Objectives

Aim

The aim of the study was to evaluate the Safety and efficacy of curcumin versus diclofenac in knee osteoarthritis.

Objective

The purpose of this study was to compare the efficacy and safety of curcumin with those of diclofenac in the treatment of knee osteoarthritis (OA).

3. Materials and Methods

Shep et al. Trials (2019): This study compared the efficacy and safety of curcumin with those of diclofenac in the treatment of knee osteoarthritis (OA). In this randomized, open-label, parallel, active controlled clinical study, 139 patients with knee OA were randomly assigned to receive either a curcumin 500-mg capsule three times daily or a diclofenac 50-mg tablet two times daily for 28 days. Patients underwent assessment at baseline and days 7, 14 and 28.

The main outcome measure was severity of pain using visual analogue scale score at days 14 and 28. Knee Injury and Osteoarthritis Outcome Score (KOOS) (At days 14 and 28), anti-flatulent effect (at day 7), anti-ulcer effect, weight-lowering effect, and patient's and physician's global assessment of therapy at day 28were included as secondary outcome measures. Safety after treatment was evaluated by recording adverse events and laboratory investigation. At days 14 and 28, patients receiving curcumin showed similar improvement in severity of pain and KOOS scale when with compared with diclofenac, and the difference was not statistically significant.

At day 7, the patients who received curcumin experienced as significantly greater reduction in the number of episodes of flatulence compared with diclofenac ($p<0.01$). At day 28, a weight-lowering effect ($P<0.01$) and anti-ulcer effect ($P<0.01$) of curcumin were None of the patients required H2 blockers in the curcumin group, and 19 patients required H2 blockers in the diclofenac group (0% versus 28%, respectively, $P<0.01$). Adverse effects were significantly less in the curcumin group (13% versus, 28% respectively, $P<0.01$. Patients and physician's global assessment of therapy was similar in the two treatment groups.

Curcumin has similar efficacy to diclofenac but demonstrated better tolerance among patients with knee OA. Curcumin can be an alternative treatment option in the patients with knee OA who are intolerant to the side effects of non-steroidal anti-inflammatory drugs

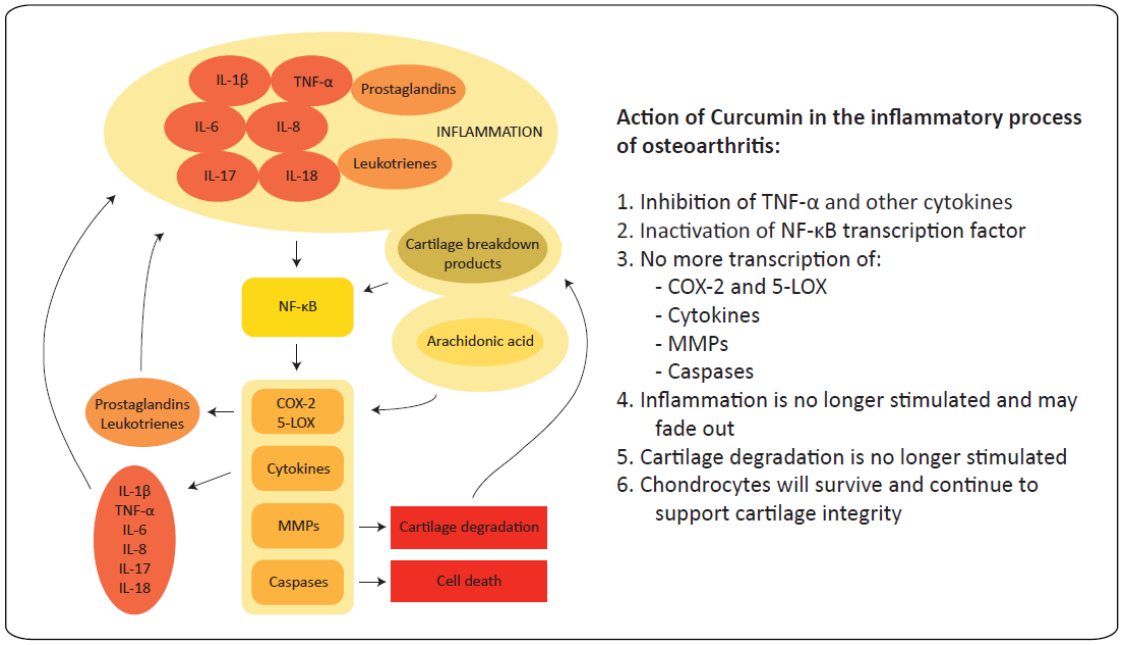

Figure 1: Schematic image of the processes in osteoarthritis, in which Curcumin could play a role to restore the healthy processes

4. Result

A total of 80 patients were enrolled as per inclusion and exclusion criteria, patients were participated in this study, and the response was 100%. Demographic and baseline characteristics in patients with knee osteoarthritis Safety and efficacy of curcumin versus diclofenac in knee osteoarthritis: a randomized open-label parallel-arm study.

The diagnosis of Osteoarthritis in the study subjects was based on the following clinical symptoms history of Nausea, vomiting, Diarrhea, Abdominal pain, Constipation, Dyspepsia, Weakness at the first day of pharmacokinetic assessment. In **Ortholord ™** Curcumin can be an alternative treatment option in the patients with knee OA who are intolerant to the side effects of non-steroidal anti-inflammatory drugs.

Table 1: Summary of adverse reactions in each treatment group

Adverse reactions	**Curcumin (N=70) n%**	**Diclofenac (N=69) N%**	**RR**	**RRLB**	**RRUB**	**NNT**
Total number of Patients experiencing AE's	9 (13%)	26 (38%)				
Dyspepsia	0	6 (8.7%)	0.08**	0	1.3	12

Nausea	6 (9%)	7 (10.14%)	0.8	0.3	2.4	64
Vomiting	0	7 (10.14%)	0.07**	0	1.1	10
Diarrhea	5 (7%)	8 (11.6%)	0.6	0.2	1.8	23
Constipation	0	6 (8.7%)	0.08**	0	1.3	12
Abdominal pain/acidity	0	19 (27.53%)	0.03**	0	0.4***	4
Flatulence	0	9 (13.04%)	0.05**	0	0.9***	8
Upper respiratory tract infection	0	5 (7.25%)	0.09**	0	1.6	14

Abbreviations: a treatment group, b control group, n number of patients in each category, N total number of patients in each treatment group, NNT number needed to treat, RR relative risk, RRLB relative risk lower boundary, RRUB relative risk upper boundary

**P <0.01 for curcumin versus diclofenac*

***Clinically significant adverse event (AE) (RR <0.5)*

****Statistically significant AE (95% confidence interval does not include 1)*

Table 2: Comparison of pain as determined by visual analogue scale in patients with knee Osteoarthritis

Visit	Curcumin (N=70)	Diclofenac (N=69)	p value
Baseline	7.8±0.63	7.81±0.73	0.79t
Day 14	4.69±0.79	4.58±0.60	0.38†
Day 28	2.20±0.81	2.20±0.61	0.98t
Change at Day 14	-3.16±0.79	-3.23±0.91	0.61t
Change at Day 28	-5.93±0.99	-5.61±0.88	0.82t

p value	P<0.01	P<0.01	
VAS reduction % ≤ 50	N=4	N=2	P=0.68f
VAS reduction % > 50	N=66	N=67	

5. Discussion

Curcumin lowers the production of prostaglandins and COX-2 in the cells of inflamed joint mucous membranes, and it lowers the number of mucous-membrane cells in a controlled manner. As such, Curcumin has a positive effect on the degenerative inflammation process in joint diseases, including rheumatoid arthritis and osteoarthritis. . Curcumin can be an alternative treatment option in the patients with knee OA who are intolerant to the side effects of non-steroidal anti-inflammatory drugs. Osteoarthritis is a degenerative joint disease that is the most common type of arthritis. Causes OA is caused by joint damage. This damage can accumulate over time, which is why age is one of the main causes of the joint damage leading to osteoarthritis. Visual analogue scale is from 0 to 10, where 0 indicates "No pain" and 10 indicate "Worst possible pain". Both treatment groups showed a significant reduction in VAS scores from their baselines. The numbers of patients having more than 50% improvement in VAS score in curcumin group and in the diclofenac group. Curcumin has similar efficacy to diclofenac but demonstrated better tolerance among patients with knee OA.

6. Safety variables

Overall patients receiving curcumin and diclofenac reported at least one AE and this difference was statistically significant (P <0.01). All reported AEs were mild and transient. The most common AEs were nausea, diarrhea, abdominal pain/acidity, and flatulence. The incidence of each AE was significantly less in the curcumin group compared with the diclofenac group. Curcumin has a positive effect on the degenerative inflammation process in joint diseases, including rheumatoid arthritis and osteoarthritis.

7. Conclusion

To conclude that Curcumin has similar efficacy to diclofenac but demonstrated better tolerance among patients with knee OA. Curcumin can be an alternative treatment option in the patients with knee OA who are intolerant to the side effects of non-steroidal anti-inflammatory drugs.

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