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Functional Outcomes of Undenatured type-2 Collagen V/S Glucosamine Supplements in the Management of Mild to Moderate Knee Osteoarthritis- a Prospective, Randomised Study

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ABSTRACT

Osteoarthritis is the second most common inflammatory arthropathy with a prevalence of 22% to 39% in India. Osteoarthritis (OA), also known as a degenerative joint illness, is a chronic, painful, and inflammatory disease that affects the joints. It is characterized by chronic joint pain, stiffness, inflexibility, swelling, narrowing of joint spaces, and formation of osteophytes. The most common medications include anti-inflammatory drugs, analgesics, weak opioids, and corticosteroids. These agents are inadequate to effectively reduce the pain or reverse the OA symptoms. Nutraceuticals are also used to ease their pain and discomfort. It can be used as an alternative therapy to avoid the negative effects of taking NSAIDs. These are considerably safe and well tolerated. Participants who met the study's eligibility requirements were enrolled and given instructions to report for a baseline evaluation. At the first treatment visit (Visit 2), selected subjects were randomly assigned and treated with UC-II or Glucosamine. On each visit day (day 30, 60, 90), subjects were followed up for medical and physical examination. The pain score assessments included WOMAC, VAS and Oxfordknee pain scores. Each patient participated in the trial by keeping a subject treatment diary that recorded side events, medication use, and product compliance. Out of 100 patients included in the study, 91 patients have completed 3 months of nutraceutical therapy for mild to moderate management of OA. Among 91 patients, 63 patients were prescribed with UC II Collagen and 28 patients were prescribed with Glucosamine supplement. The patients were analysed for improvement in symptoms by using 3 standard questionnaires to assess the outcomes. Patient follow up was done to collect data and results were statistically analyzed. It was observed that both the supplements had efficacy in improvement of symptoms of OA i.e., pain, stiffness and physical function difficulties. Upon comparison of efficacy of UC II Collagen vs Glucosamine, it revealed that there is no statistical significant difference between their outcomes. The study demonstrates that upon administration of nutraceutical i.e., UC II Collagen or Glucosamine, for a period of 3 months have significantly shown to improve symptoms of Knee OA. Use of such supplements has resulted in fewer use of analgesics. Both Undenatured Type II Collagen and Glucosamine display equivalent efficacy and yield functional outcomes among patients afflicted with Grade 2 and Grade 3 OA in the knee joints, and found to improve QoL.

Keywords: Medicover Hospital, QoL, arthropathy, OA symptoms, WOMAC, VAS and Oxford

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1. Introduction

Osteoarthritis (OA) is a common degenerative disease of joints, one of the most common rheumatology problems and leading causes of disability. It is characterized by chronic joint pain, stiffness, inflexibility, swelling, narrowing of joint spaces, and formation of osteophytes. Osteoarthritis is a disease of cartilage characterized by breakdown of articular cartilage and proliferative changes of surrounding bones, loss of articular cartilage, hypertrophy of bone at the margins, subchondral sclerosis, and range of biochemical and morphological alterations of the synovial membrane and joint capsule.^[2]



Epidemiology:

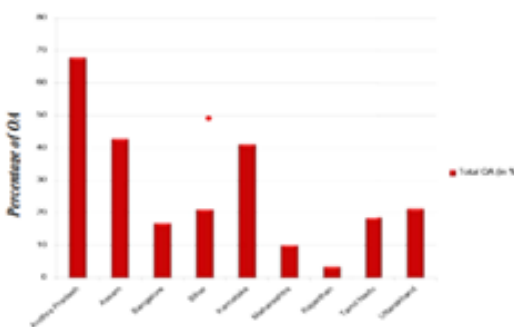


Fig.1. Prevalence of OA in India

Globally OA ranks eighth in all diseases and covers around 15% proportions among all musculoskeletal problems. OA accounts as the most prevalent musculoskeletal disease among the world and is the most common reason for joint disability in approximately 100 million people worldwide having age over 45 years, which is approximately 15% of all musculoskeletal disorders.

Etiology:

The etiology of OA is multifactorial and complex. The most common risk factors for the development of OA

include age, obesity, sex, occupation, participation in certain sports, history of joint injury or surgery, developmental abnormalities and genetic predisposition³.

Pathophysiology:

OA is a degenerative joint disease. Development of OA is based on local mechanical influences, genetic factors, inflammation, and aberrant chondrocyte function. At a molecular level, OA pathophysiology involves the interplay of dozens, if not hundreds, of extracellular and intracellular molecules with roles including chondrocyte regulation, phenotypic changes, proteolytic degradation of cartilage components, and interactions between cartilage, underlying subchondral bone, and the joint synovium. OA most commonly begins with damage to articular cartilage, through trauma or other injury, excess joint loading from obesity or other reasons, or instability or injury of the joint that causes abnormal loading. In response to cartilage damage, chondrocyte activity increases in an attempt to remove and repair the damage. Depending on the degree of damage, the balance between breakdown and resynthesis of cartilage can be lost, and a vicious cycle of increasing breakdown can lead to further cartilage loss and apoptosis of chondrocytes. Normal cartilage turnover helps repair and restore cartilage in response to demands of joint loading and during physical activity. There is an increased appreciation of the role of tissues beyond cartilage, within the joint and surrounding it, subchondral bone. Subchondral bone undergoes pathologic changes that may precede, coincide with, or follow damage to the articular cartilage.

Diagnosis:

The diagnosis of OA is based on the combination of typical mechanical symptoms and physical joint findings in an individual with risk factors for the development of OA. No diagnostic tool for OA has been validated for use in routine clinical practice. The individual may present with pain in more than one joint. The pain associated with OA is of gradual onset and worsened by activity. In Knee OA activity related pain is experienced which becomes worse towards end of the day. Pain is relieved by rest and varies in severity.

Prognosis:

The prognosis for patients with primary OA is variable and depends on the joint involved. If a weight bearing joint or the spine is involved, considerable morbidity and disability are possible. In the case of secondary OA, the prognosis depends on the underlying cause.

2. Material and Methods

Study site: This study was conducted at OP Orthopaedics department at Medicovert Hospitals, Madhapur, Hyderabad.

Study Period: This study was conducted for a period of 6 months.

Ethical Approval: The study was approved by the Institutional Ethical Committee of Medicover hospital, Madhapur, Hyderabad.

Study Criteria: INCLUSION CRITERIA:

Inclusion Criteria: Patients aged between 30-75 years old with mild to moderate Knee OA based on radiographic evidence

- VAS score ≥ 40 mm at the baseline
- WOMAC score above 10
- Oxford Knee Score < 40
- Chronic stages of knee pain
- Availability for duration of study period at least 3 months
- Subject agrees not to start any new therapies for OA during the course of the study
- Able to give informed consent

Exclusion criteria:

- Inflammatory arthropathy- Rheumatoid arthritis, Gouty arthritis
- Acute or chronic sepsis in the knee
- Patients with recent history of knee trauma and fractures
- Neuropathic joint, pain in non-target joint
- Other pathological lesions on X rays of the joint
- Expectation of Surgery in next 3-4 months
- Prolonged immobilization
- Cartilage reconstruction procedure in the target knee

Tools used:

- Microsoft Excel
- Google Sheets

Type of Study: This is a prospective observational study.

Source of data:

Data was collected from a prospective series of patient's case sheet who were consulting the OP Orthopaedic department of Medicover Hospital, Madhapur, Hyderabad.

Data collection:

- Data collection started from December 2022.
- Participants who met the study's eligibility requirements were enrolled.
- Patient Demographics, Chief Complaint, Laboratory Evaluations, Treatment Chart were collected

Data analysis:

- Patients were classified according to Age, Gender, and supplement prescribed
- Medications were assessed on different parameters
- Follow up with the patients was done.

3. Results and Discussion

A prospective and comparative study was conducted to assess the functional outcomes of nutraceuticals in the management of patients with mild to moderate Knee OA. The study was carried out for a period of 6 months from December 20th 2022 to June 20th 2023. To carry out this

study data was collected from Orthopaedic out Patient Department of Medicover Hospital, Hitech city. It was conducted through questionnaire form i.e., VAS, WOMAC and Oxford Knee Score Scales in a patient profile form. The data collected from the patient profile forms was analyzed using Microsoft excel and software Among the total participants (100), 63 participants are prescribed with Undenatured Type II Collagen supplement and 28 participants are prescribed with Glucosamine supplement. The number of drop outs were 9. Hence, we will be considering these 91 patient's data as 100 %, while analyzing the results of Undenatured Type II Collagen & Glucosamine supplements in the management of knee mild to moderate knee OA.

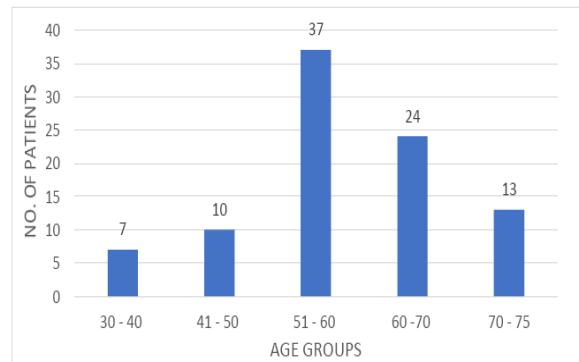


Fig.2. Overall Distribution of Data According to Age Groups- Graphical representation

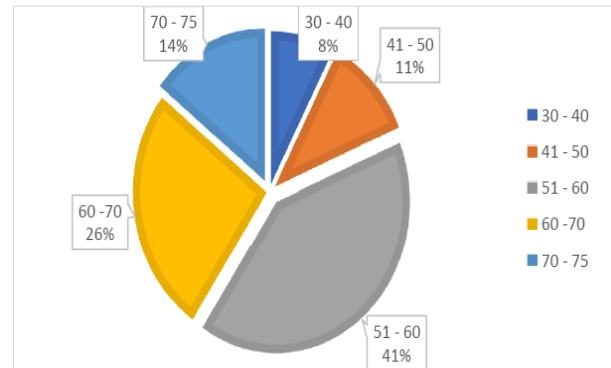


Fig.3. Overall Distribution of Data According to Age Groups- Pie Chart

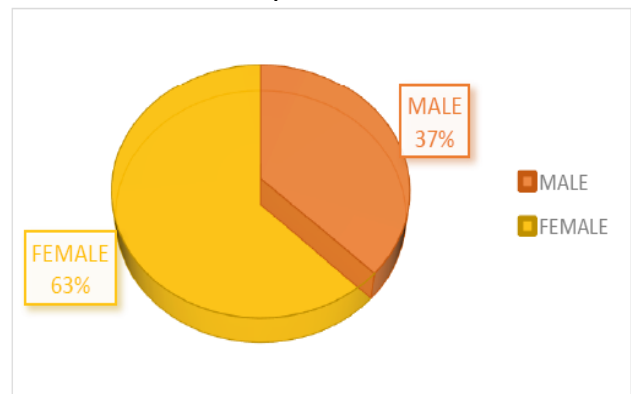


Fig.4. Overall Distribution of Data According to Gender

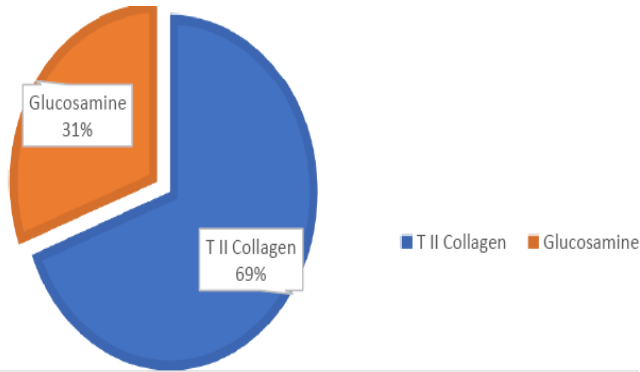


Fig.5. Prescribing Pattern of Supplements for Management of OA

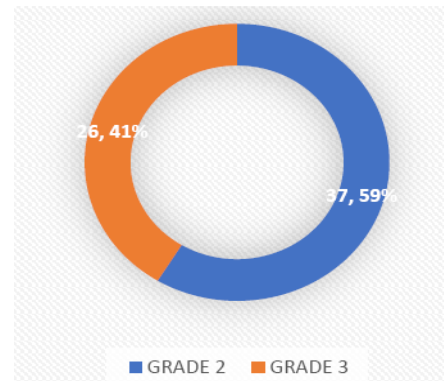


Fig.9. Distribution of UC II Collagen Specific Data Based on Grade of OA

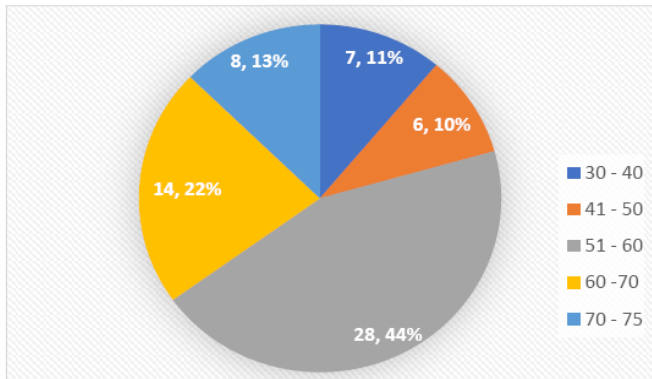


Fig.6. Distribution of UC II Collagen Specific Data According to Age Group

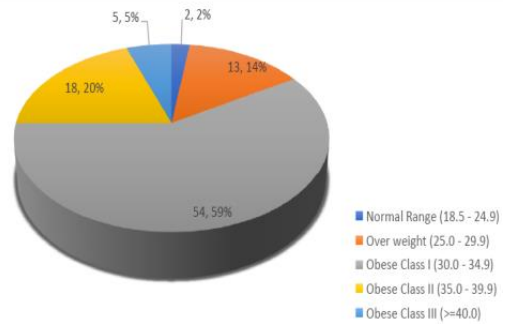


Fig.10. Overall Distribution of Data Based on BMI

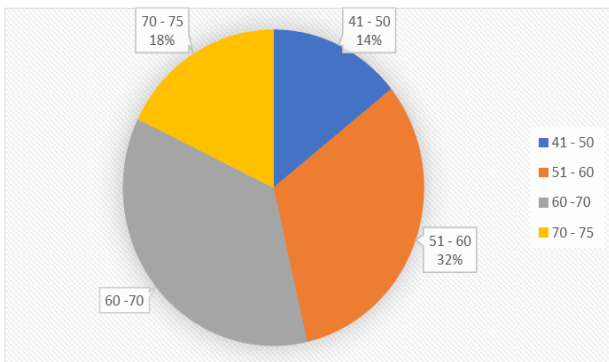


Fig.7. Distribution of Glucosamine Specific Data According to Age Group

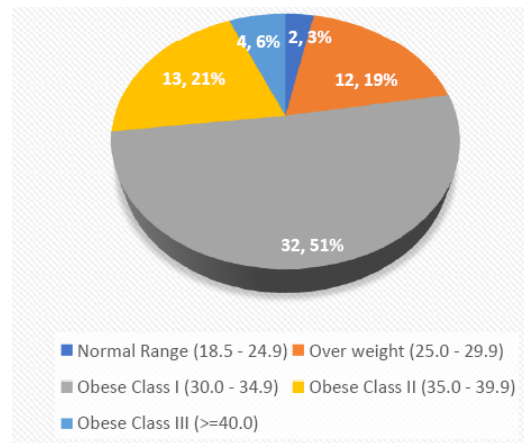


Fig.11. Distribution of UC II Collagen Specific Data Based on BMI

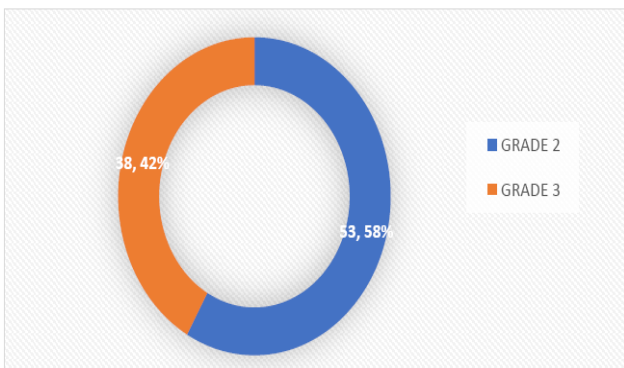


Fig.8. Overall Distribution of Data According to Grade of OA

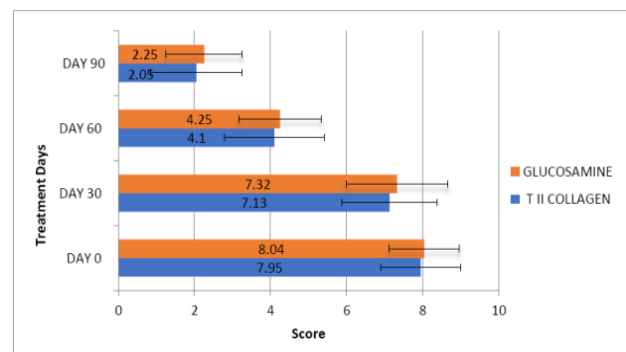


Fig.12. Changes in VAS Scores at Day 90 from Baseline - Collagen vs Glucosamine

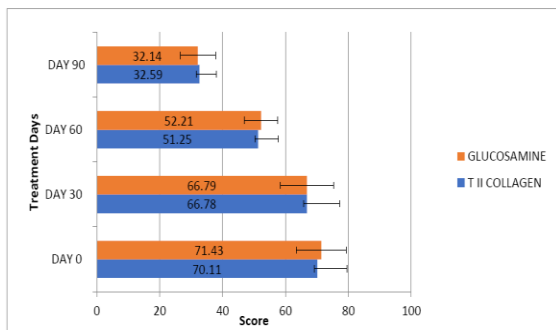


Fig.13. Changes in Total WOMAC Score at Day 90 from Baseline – Collagen vsGlucosamine

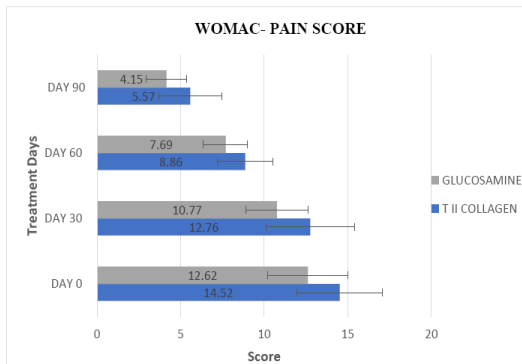


Fig.14. Changes in WOMAC- Pain Score at Day 90 from Baseline – Collagen vsGlucosamine

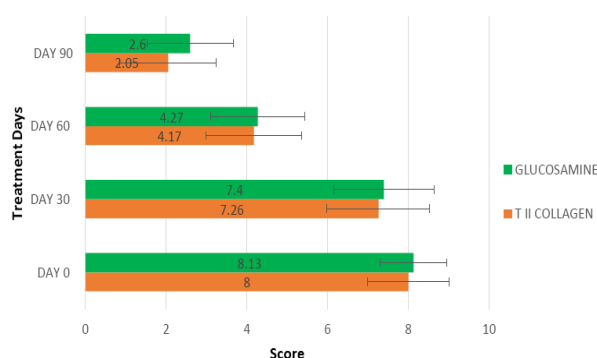


Fig.15. Changes in VAS Scores at Day 90 from Baseline - Collagen vs Glucosamine

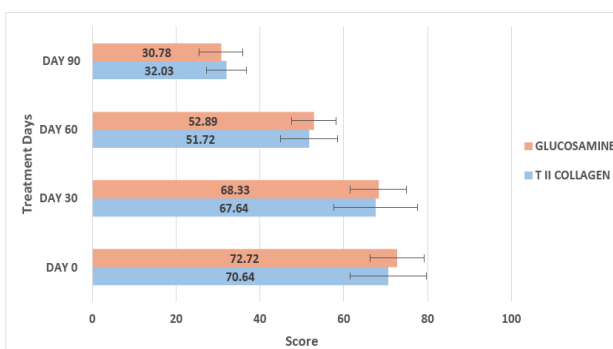


Fig.16. Changes in Total WOMAC Score at Day 90 from Baseline – Collagen vsGlucosamine

Discussion

OA is the most common form of arthritis, and it is often associated with significant disability and an impaired quality

of life, has enormous implications in terms of personal suffering and costs to society. The knee is one of the joints most frequently affected by OA. There are no curative therapies currently available for OA, individualized treatment programs are available to help relieve pain and stiffness, and to maintain and/or improve functional status. Numerous nutraceuticals have been developed over the past decades to combat joint impairment, primarily due to OA. This was mainly done to avoid invasive techniques and therapies such as NSAIDs that would lead to significant adverse effects. A prospective, randomized study was conducted in patients with mild/moderate Knee OA, in a time period of 6 months in a tertiary care hospital, Medicare Hospitals, Madhapur. Cases were collected from OP department, and each patient was followed up each month for 3 months. A patient profile form was developed containing questionnaire to assess the outcomes of supplements prescribed i.e., Undenatured Type II Collagen or Glucosamine, and the results were analyzed. To evaluate the impact of these nutraceuticals on the participants' functional outcomes, three questionnaires were used: VAS, WOMAC and Oxford knee score scales. Scores of the scales were documented during each patient follow up at Day 0, Day 30, Day 60 and Day 90. The mean ± SD of scores of both patient groups were calculated for each follow up and analysed in our study, out of 91 patients, 63 patients were prescribed with UC II Collagen and 28 patients were prescribed with Glucosamine supplement, 1 tablet daily for period of 90 days. The number of prescriptions of UC II Collagen are more than the number of prescriptions of Glucosamine.

4. Conclusion

A prospective, randomized study was conducted for a period of 6 months to analyse the functional outcomes of Undenatured Type-II Collagen V/s Glucosamine supplements in the management of mild to moderate knee OA, in a tertiary care hospital. Based on the results of this study, the following conclusions were made: glucosamine & Undenatured Type II Collagen have demonstrated the capacity to reduce the prevalence of painful and inflamed joints, inducing noteworthy improvements in VAS, WOMAC & Oxford knee scores. Both Undenatured Type II Collagen and Glucosamine display equivalent efficacy and yield functional outcomes among patients afflicted with grade 3 and grade 2 osteoarthritis in the knee joints. Both Undenatured Type-II Collagen and Glucosamine are safe and improve Quality of life in knee OA patients. These nutraceuticals are beneficial in patients to improve symptoms such as pain and swelling and can decrease requirement of analgesic consumption.

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