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Prescription Pattern of Drugs Used in Osteoarthritis among Patients in a Tertiary Health Care Centre

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ABSTRACT

Introduction– Osteoarthritisis a progressive degenerative disorder affecting cartilage, bone, synovium, muscles and ligaments, resulting in stiffness, loss of mobility, swelling and pain. The disease mainly affects weight bearing joints like hip, knee, lower back, neck, fingers, base of thumb and great toe. Age is the most common risk factor. Obesity and trauma also increase the risk. The main objective in the management of osteoarthritis is to reduce symptoms and progression of structural changes and thereby to delay or avoid the need for hip or knee replacement. Management of osteoarthritis includes non-pharmacological, pharmacological and surgical interventions. NSAIDs are the most widely prescribed drugs for osteoarthritis and they provide symptomatic relief.Topical preparations of NSAIDs are also prescribed to reduce gastrointestinal side effects,and systemic toxicity.SYSADOA group of drugs are Glucosamine sulphate, Glucosamine hydrochloride, Diacerein, Chondroitin sulphate and Hyaluronic acid. These drugs improve patient symptoms, reduces cartilage degradation and decreases the occurrence of gastrointestinal side effect when compared to NSAIDs. This study aims to assess the drug utilization pattern among osteoarthritis patient in a tertiary care hospital.

Objectives -To analyze the prescription pattern of drugs used in the treatment of osteoarthritis in a tertiary care hospital.

Methodology – This was a cross sectional study, conducted in the Rheumatology clinic under the Department of Internal medicine,Govt. Medical College Thrissur. Study period was 1 year from February 2021 to January 2022 with a sample size of 100. Patients diagnosed with osteoarthritis & satisfying inclusion criteria were taken. Study was initiated after getting IEC approval. Patients were enrolled after taking informed consent. Relevant data including demographic parameters, co-morbidities, duration of illness, drugs prescribed were recorded. Data were entered to windows excel sheets and analyzed using SPSS V.26 software. Qualitative data was expressed in percentage. Quantitative data was expressed as mean and standard deviation.

Results – Based on inclusion criteria, a total of 100 patients were included in the study. Among 100 study subjects 58% were females and 42% were males. Majority of the patients belonged to the age group of 50-59 years. The mean age of the study population was 58.07 $\pm$ 10.245. Knee joint (66%) was most commonly involved followed by hip (21%) in osteoarthritis.NSAIDs were most commonly prescribed for alleviation of pain in osteoarthritis.Among NSAIDs Aceclofenac (44%) was most commonly prescribed followed by Diclofenac (30%). Topical NSAIDs like Diclofenac gel were widely prescribed along with systemic NSAIDs. SYSADOA were next commonly prescribed drug for osteoarthritis along with NSAIDs. Opioids like Tramadol alone or combinationof Tramadol and Paracetamol (NSAIDs) were prescribed in 20% of study subjects. GABA analogues like Gabapentin, Pregabalin and their FDCs were prescribed in 31% of study population to relieve neuropathic pain associated with osteoarthritis. Oral steroids like Deflazacort were prescribed only in 10% of cases. Gastroprotective agents like PPI and H_2 Blockers were also prescribed to reduce NSAID induced gastritis. Among these Pantoprazole was widely prescribed.

Conclusion -The knee joint is most commonly involved in osteoarthritis. Females and those in the elderly age group were more commonly affected. NSAIDs were the most widely prescribed drugs. Among NSAIDs Aceclofenac was the most commonly prescribed drug. SYSADOA, GABA analogues, steroids and supplements were also employed as adjunctive therapy.

Key words -Osteoarthritis, NSAIDs, SYSADOA, Rational Drug Use, Prescription pattern

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I. INTRODUCTION

Osteoarthritis is a progressive degenerative disorder of multi-factorial etiology.The pathological changes include destructionofarticularcartilage; subchondral sclerosis associated with synovialchanges.(1)Osteoarthritis (OA), as a major cause of chronic pain and lower extremity disability among the elderly is being increasingly observed in both developed and developing countries. It has increased predilection for lower extremity joints such as the knee and hip.(2,3) Although age is the strongest predictor of the development of osteoarthritis, obesity, trauma, physically demanding occupations and activities also increase the risk for OA.(4)

Pain relief plays a key role in the treatment of osteoarthritis, therefore management of osteoarthritis is largely palliative focusing on symptomatic relief most commonly targeting pain.(5) The main objectives in the management of osteoarthritis are to reduce symptoms and improve functionality or at least reduce the progression of structural changes and thereby delay or avoid the need for prostheses.(6)

Management of OA starts with the simple approaches like weight reduction (in obesity), exercise, lifestyle modification,use of analgesics and topical agents.(7) Therapeutic measures consist of nonpharmacological (e.g., patient education and physical therapy), pharmacological (nonsteroidal anti-inflammatory drugs andsymptomatic slow-acting drugs in osteoarthritis) and surgical treatments (orthopedic surgery including joint replacement) which is the last resort.(8)

Despite the fact that NSAIDs provide only symptomatic relief and don't prevent progression of the disease, they remainthe most widely prescribed drugs for OA.(9)But, their long-term use is associated with gastrointestinal ulceration, vascular adverse events and other complications.(10)Application of topical NSAIDshas been found to reduce both gastrointestinal adverse reactions and systemic toxicity.(11)COX-II inhibitors were used as an alternative to traditional NSAIDs in patients with upper gastrointestinal bleed and peptic ulcer.(12)However they have now gone into disuse due to their serious adverse drug reaction. Paracetamol has got better gastrointestinal safety profile and hence it has been recommended as the initial drug of choice for symptomatic relief in OA.(13,14) NSAIDs should be considered only in patients unresponsive to Paracetamol.(15)

Safe and effective alternative treatments are needed to providesymptomatic improvement and disease modifying effects in OA. So, second-line drugs such as symptomatic slow acting drugs for OA (SYSADOA) which includes Glucosamine sulfate, Glucosamine hydrochloride, Chondroitin sulfate, Hyaluronic acid and Diacerein are used frequently. Safety and efficacy of SYSADOA for symptom relief and possible structure-modifying effects have been proven in a lot of clinical trials.(16–19)Symptomatic improvement, reduced cartilage destruction and decreased occurrence of gastrointestinal adverse events are noted with SYSADOA, compared to NSAIDs.(6,17)There are a lot of misconceptions regarding the effectiveness of disease modifying drugs in OA, even though OARSI (Osteoarthritis Research Society International) recommendations have laid down the importance of the use of these drugs in OA.(14,15)

A drug utilization study is considered to be one of the most effective methods to assess and evaluate the prescribing attitude of physicians. There are very few studies which describe drug utilization in osteoarthritis despite the considerable high socio-economic impact of OA in our country. Thus, this cross sectional study was carried out to analyze the prescribing pattern and frequency of the use of drugs in the treatment of OA and to provide constructive feedback to prescribing clinicians as prescription-based survey is considered to be one of the most effective methods to assess and evaluate the prescribing attitude of clinicians.(20,21)

OBJECTIVES

To analyze the prescription pattern in patients with osteoarthritis in a tertiary care hospital

METHODOLOGY

Study Design – Cross sectional study

Study Setting –Rheumatology clinic under the Department of Internal Medicine, Govt. Medical College Thrissur, Kerala.

Study Participants – Patients who are diagnosed with osteoarthritisattending the Rheumatology clinic under the Department of Internal Medicine

Inclusion Criteria

a. All patients who have given written informed consent to take part in the study
b. Patients above 18 years of age of either sex
c. Patients diagnosed with osteoarthritis with or without co-morbidities

Exclusion Criteria

a. Patients who are not willing to participate in study
b. Patient less than 18 years of age

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c. Patients with nodal erosive osteoarthritis hand and spinal osteoarthritis

Study Period – 12 months, February 2021 to January 2022

Sample Size

Sample size calculated from parent article.(22)
According to the formula

$$n = \frac{4*p*q}{d^2}$$

$$n = \frac{4*35*65}{49}$$

$$= 185$$

So, we can consider sample size around 200
where p=35 i.e., percentage of osteoarthritis patient prescribed with NSAID
q = (100-p) = 65
d = 20% of p = 7

Due to limitation of patients in hospital due to COVID 19 pandemic and based on theaverage number of patients attending theRheumatology clinic, under the Department of Internal Medicine in the previous year, sample size will be considered to be around 100.

Sampling Method

Consecutive sampling method in which every subject meeting inclusion and exclusion criteria is selected until the required sample size is achieved.

Study Procedure

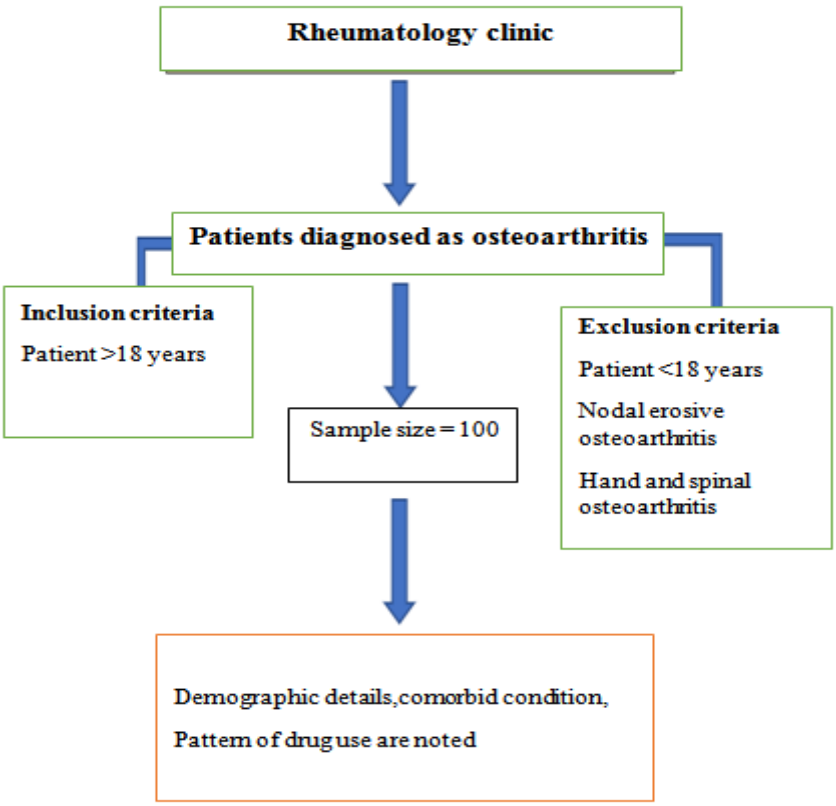
The study was initiated after approval from the Institutional Ethics Committee, Government Medical College, Thrissur. Patients who were diagnosed with osteoarthritis & satisfying inclusion criteria were enrolled in the study. Informed written consent was obtained from all patients. Patient details like age, gender, duration of illness, comorbid conditions, drugs prescribed were collected.

Data Analysis

Data was entered in Windows MS EXCEL sheets and analysed using SPSS V.26 software. Qualitative data was expressed in percentage. Quantitative data was expressed as mean and standard deviation.

II. RESULTS

Overview of study procedure



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2.1 Demographic characteristics

2.1a Age wise distribution of study population

The age wise distribution of the study population revealed that the maximum number of patients belonged to the age group of 50-59 years. 35% belonged to this group. 27% belonged to60-69years. The mean age of the study population was 58.07±10.245.

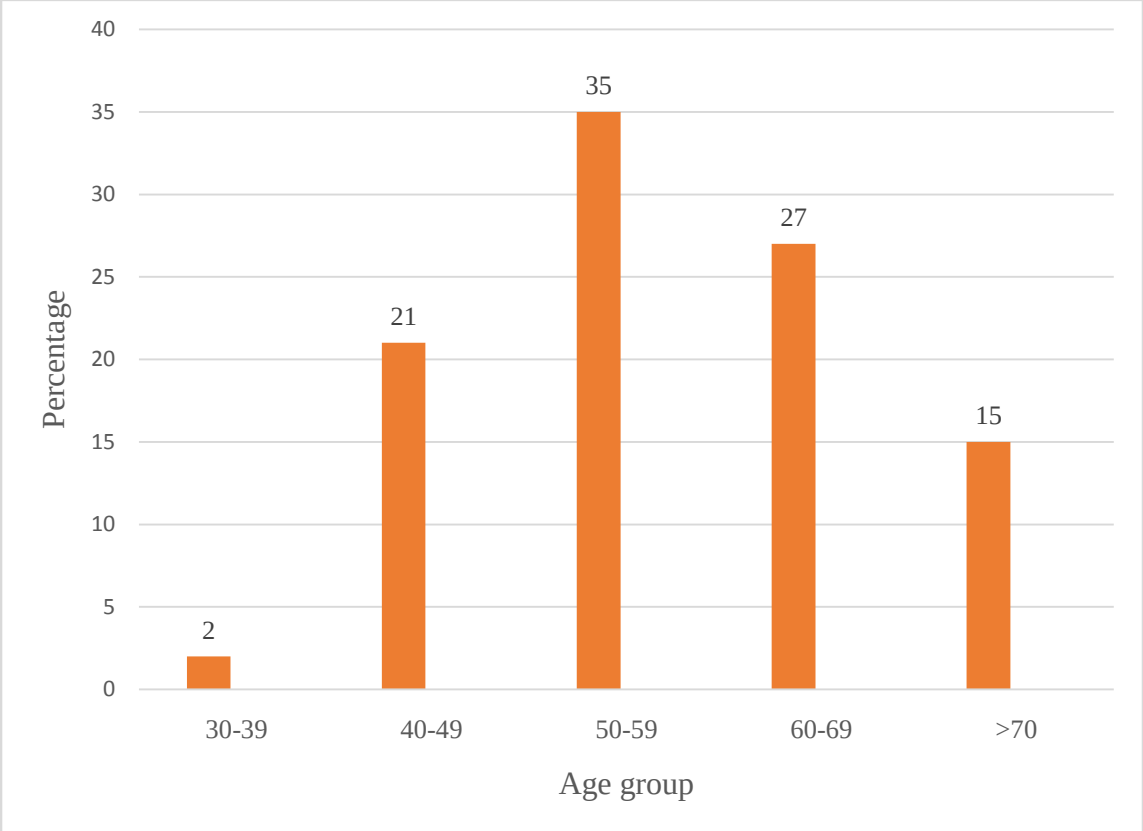

Figure 2 - Age wise distribution of study population

2.1b Gender wisedistribution of study population

As shown in the figure, among the 100 study subjects, 58% were females and 42% were males.

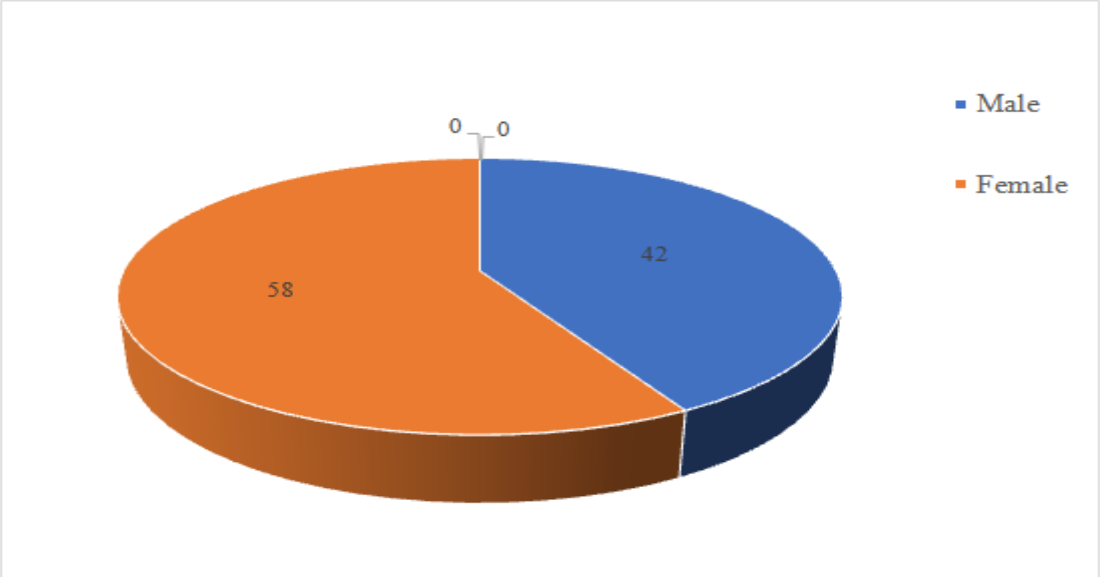

Figure 3 - Gender wise distribution of the study population

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2.1c Occupational distribution among study population

From the figure below, 45% were unemployed. Housewives were also included in the unemployed group, followed by unskilled workers.

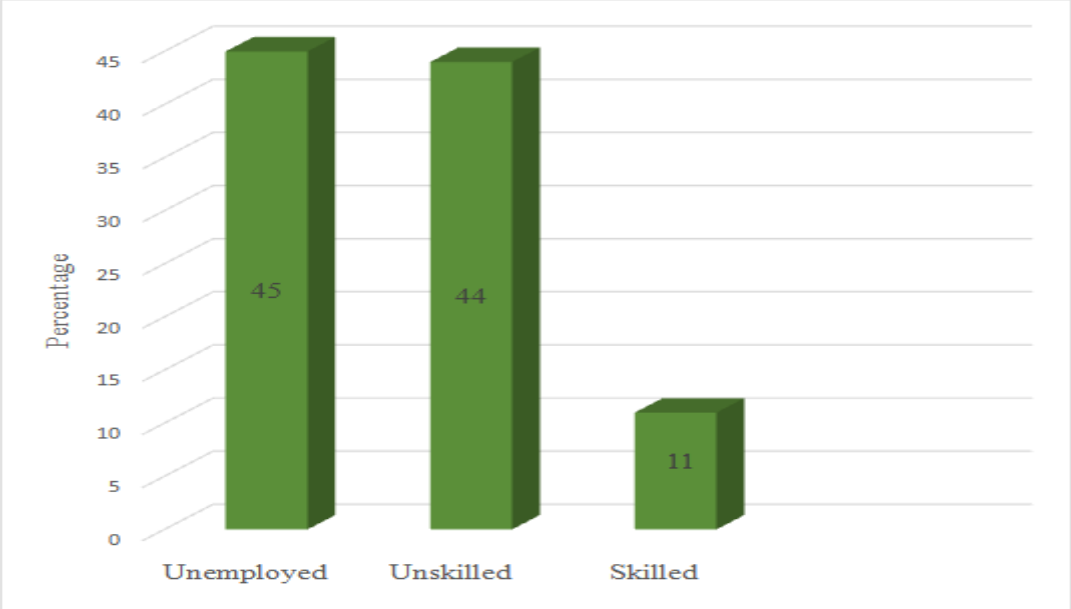

Figure 4- Occupational distribution among study population

2.2 BMI of study population

According to the figure below, 51% patients were overweight,43% normal weight while only 4% belonged to Class 1 obesity.

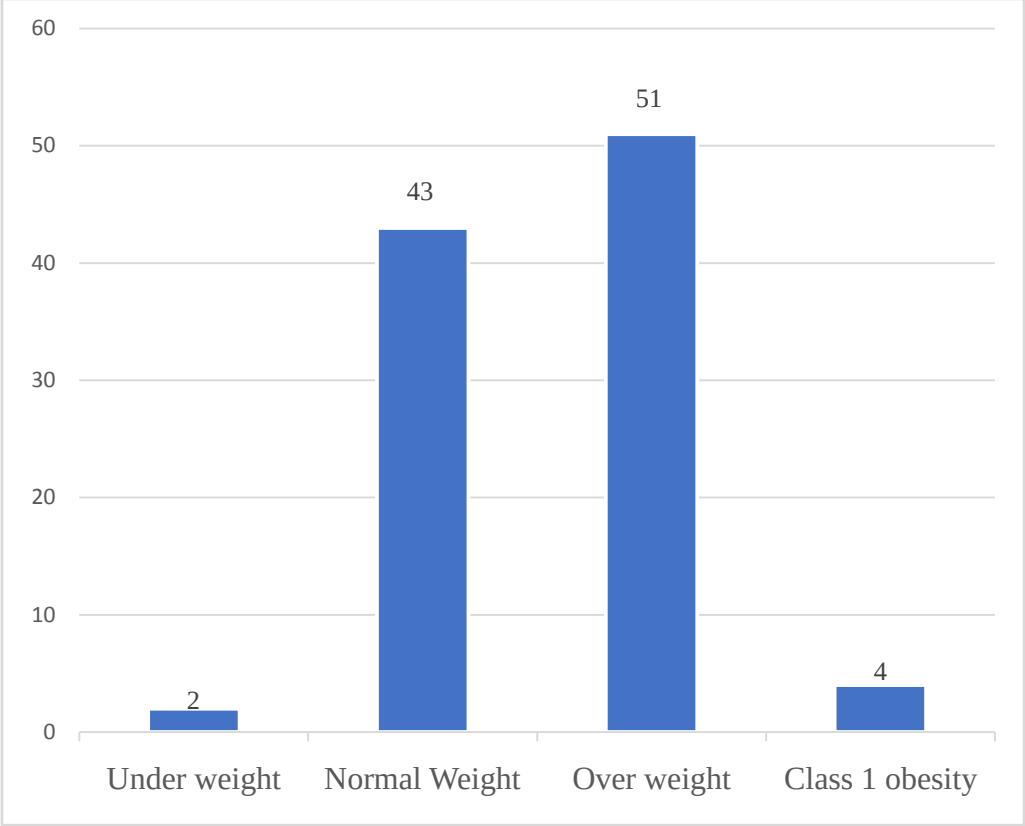

Figure 5 - BMI of study population

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2.3 History of trauma among study population

39% of the study population had a previous history of trauma.

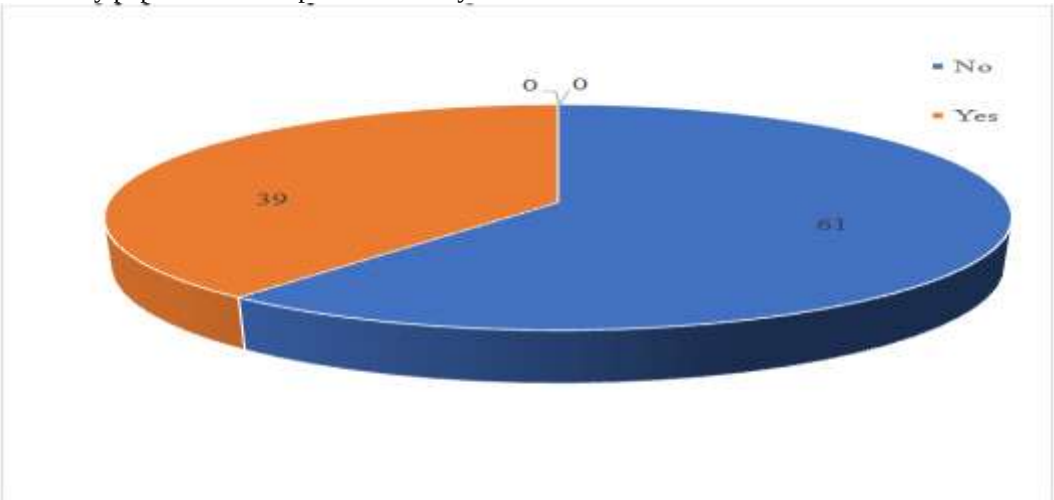

Figure 6–History of trauma among study population

2.4 Pattern of comorbid conditions among study population

Among 100 patients with osteoarthritis,60%had comorbidities and 32% had multiple comorbidities. Dyslipidaemia (33%) followed by Hypertension (31%) were the most common comorbidities. Diabetes was found in 18% patients.

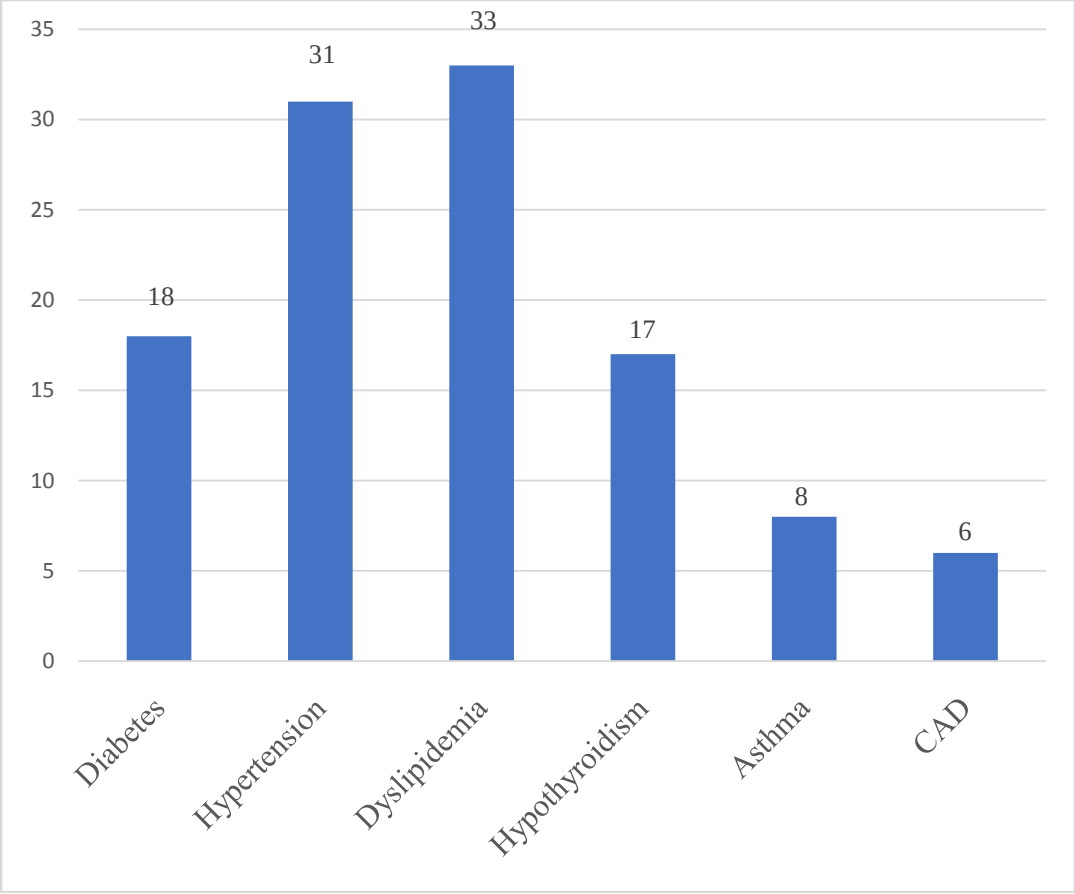

Figure 7 - Pattern of comorbid conditions among study population

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2.5 Diagnosis

2.5a Site distribution of study population

From the figure below, among the study population, most common site of osteoarthritis was knee (66%) followed by hip (21%).

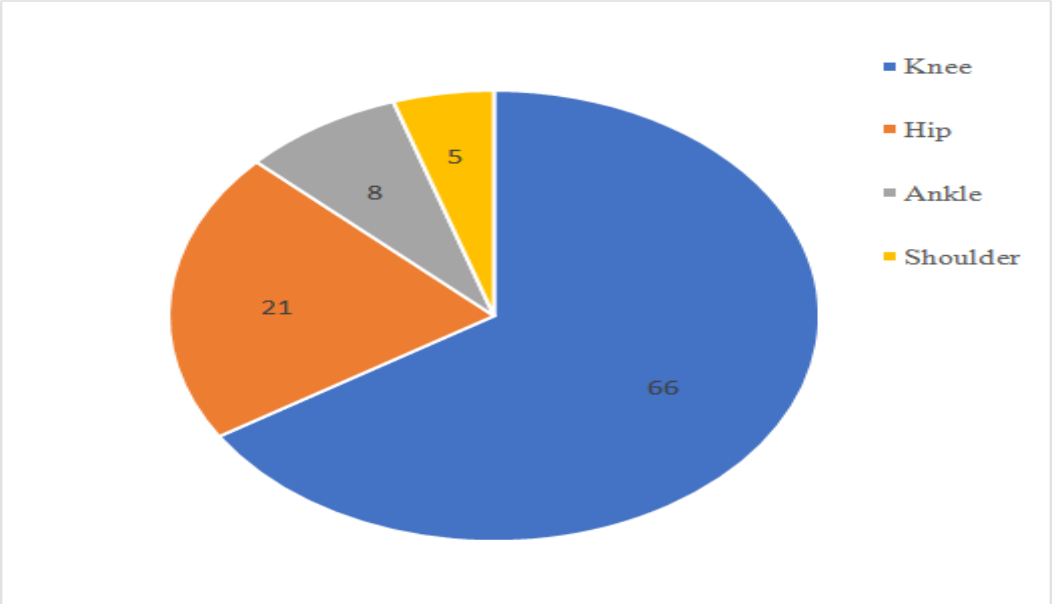

Figure 8 - Site distribution of study population

2.5b Laterality

From the figure below, 55% of the study population had unilateral distribution while 45% had bilateral distribution.

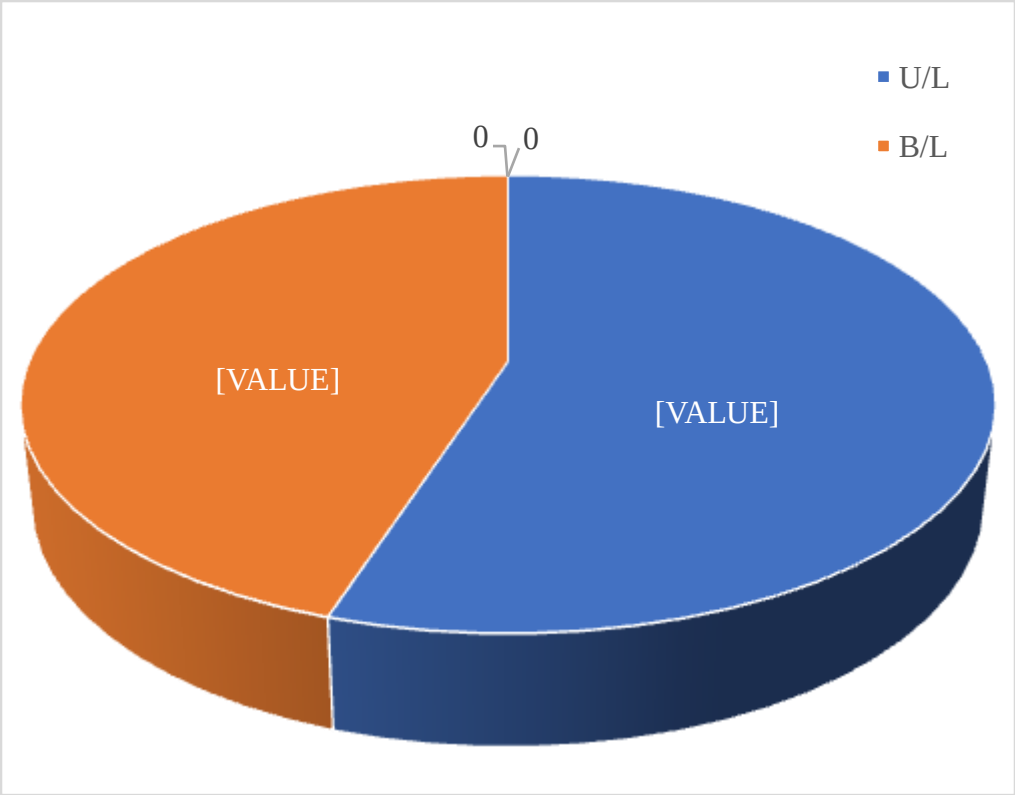

Figure 9 - Laterality

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2.6 Prescription Detail

2.6a Drug prescribing pattern

From the figure below, 54% received dual therapy, which includes analgesics and SYSADOA combination, analgesics and GABA analogues combination and analgesics and steroid combination (40%+12%+2% respectively). 20% patients with osteoarthritis received multiple therapy while 26% patient received only analgesics.

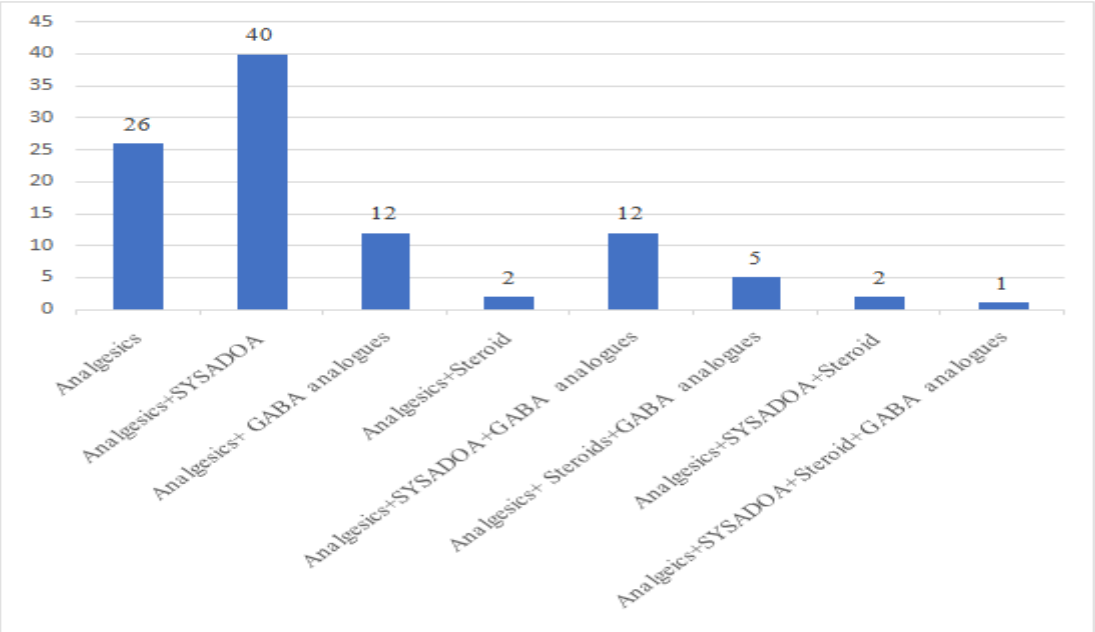

Figure 10 -Drug prescribing pattern

2.6b Pattern of use of NSAIDs among study population

From the figure below, Aceclofenac (44%) was the most commonly prescribed followed by Diclofenac (30%).

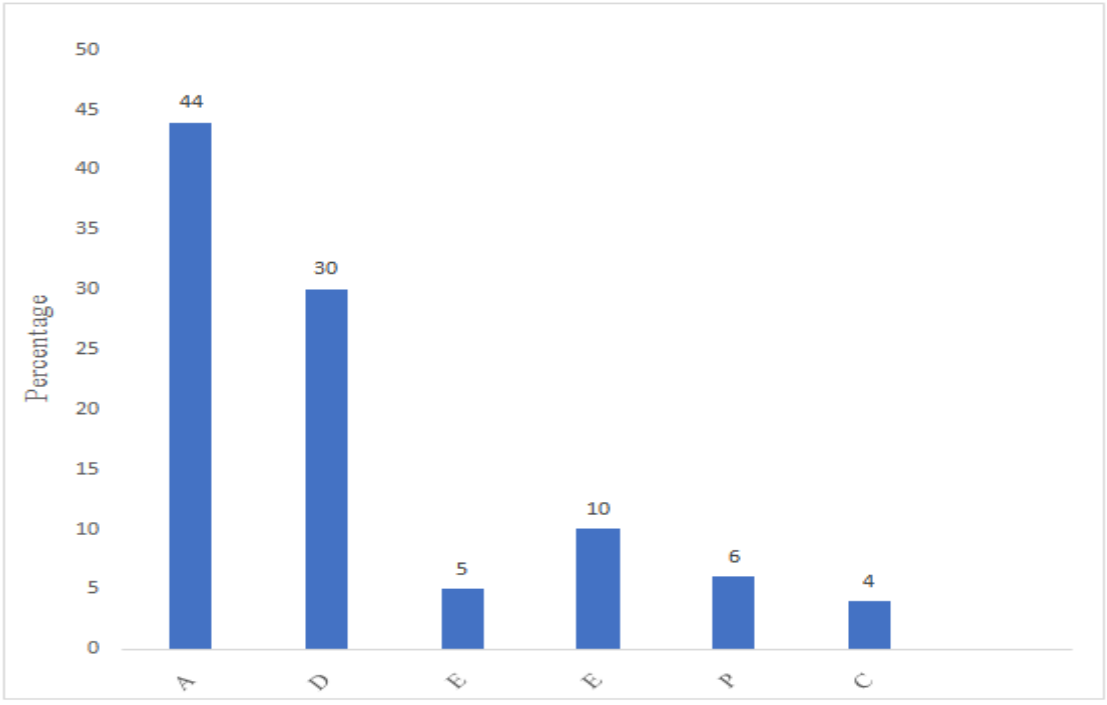

Figure 11 - Pattern of use of NSAIDs among study population

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2.6c Pattern of use of topical NSAIDs among study population

As shown in the figure, topical NSAIDs mainly Diclofenac gel was prescribed in 68% patients.

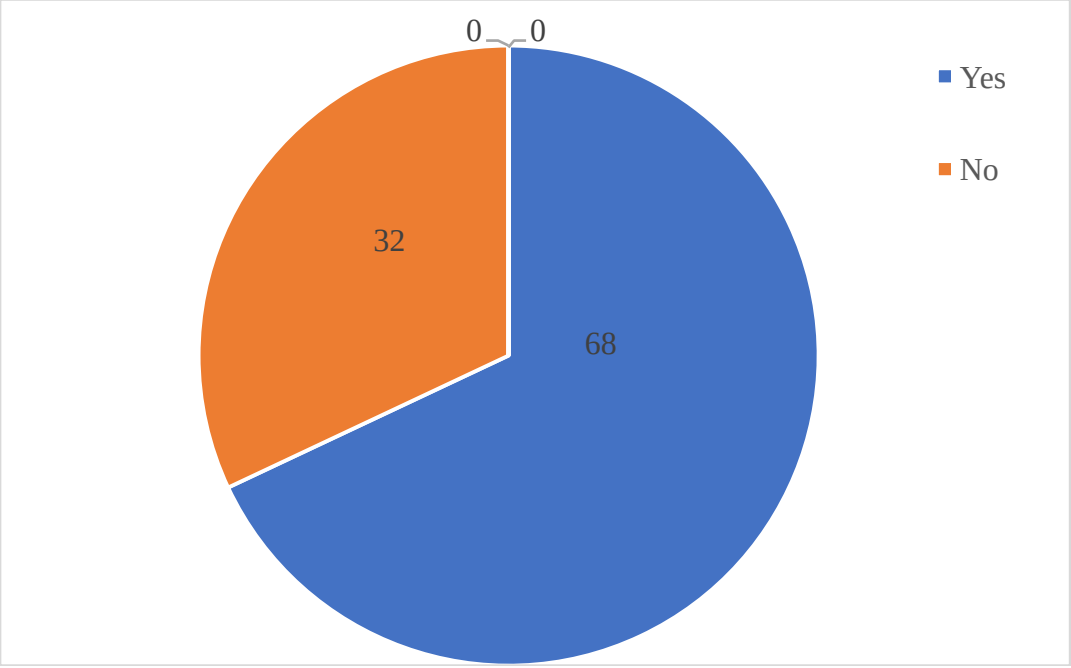

Figure 12 – Pattern of use of topical NSAIDs among study population

2.6d Pattern of use of opioids among study population

From the figure below, only 20% patients with osteoarthritis were prescribed opioids, mainly Tramadol.

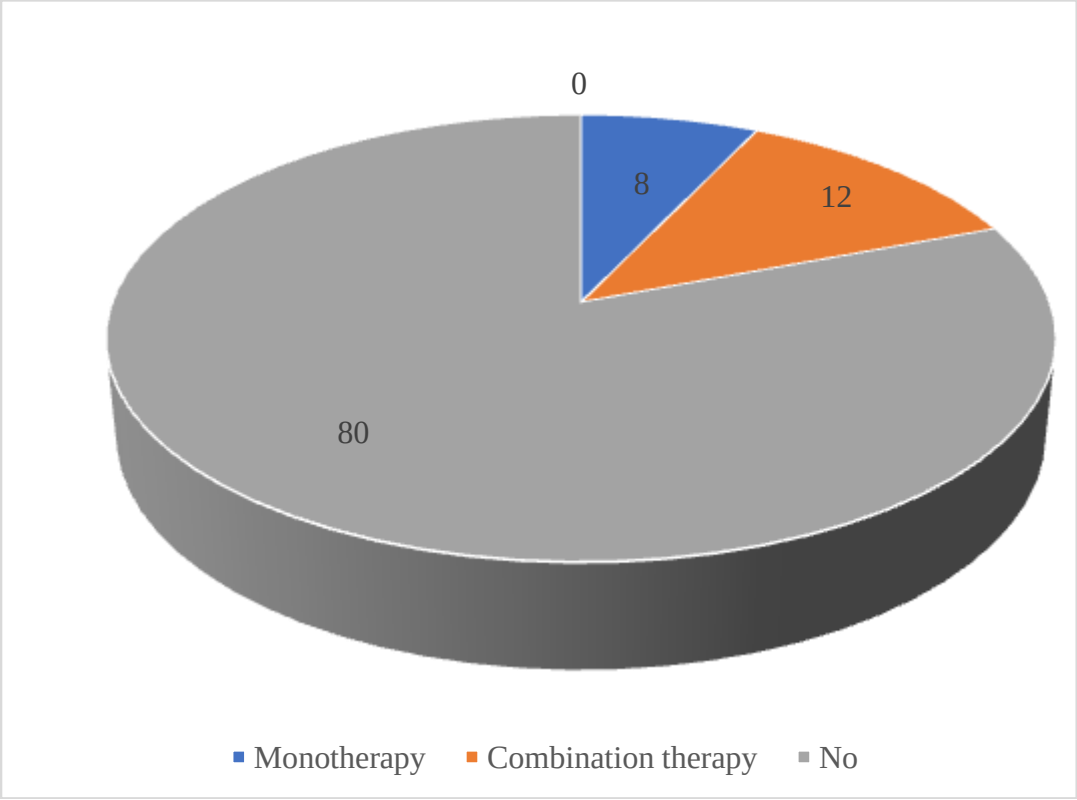

Figure 13 -Pattern of use of opioids among study population

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2.6e Pattern of use of SYSADOA among study population

From the figure below,55% of patients with osteoarthritis prescribed SYSADOA, among this 25% of the patients received FDC of SYSADOA, 18% and 12% received Glucosamine and Diacerin, respectively.

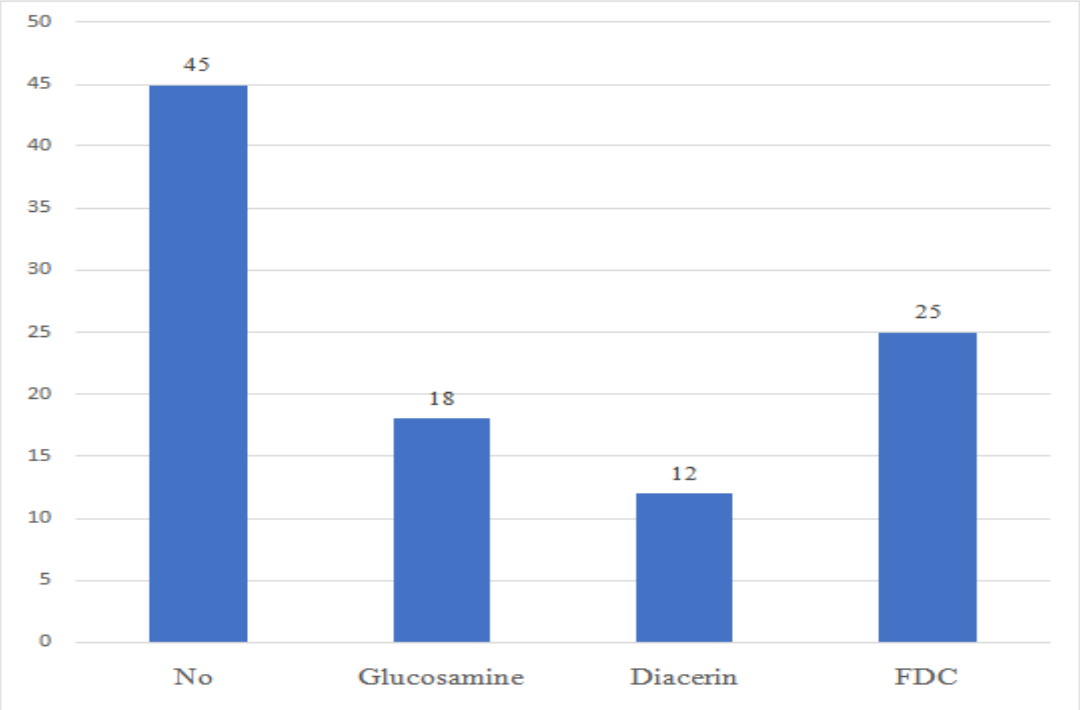

Figure 14 -Pattern of use of SYSADOA among study population

2.6f Pattern of use of corticosteroids among study population

As shown in the figure, only 10%of patients with osteoarthritis prescribed steroids, mainly Deflazacort.

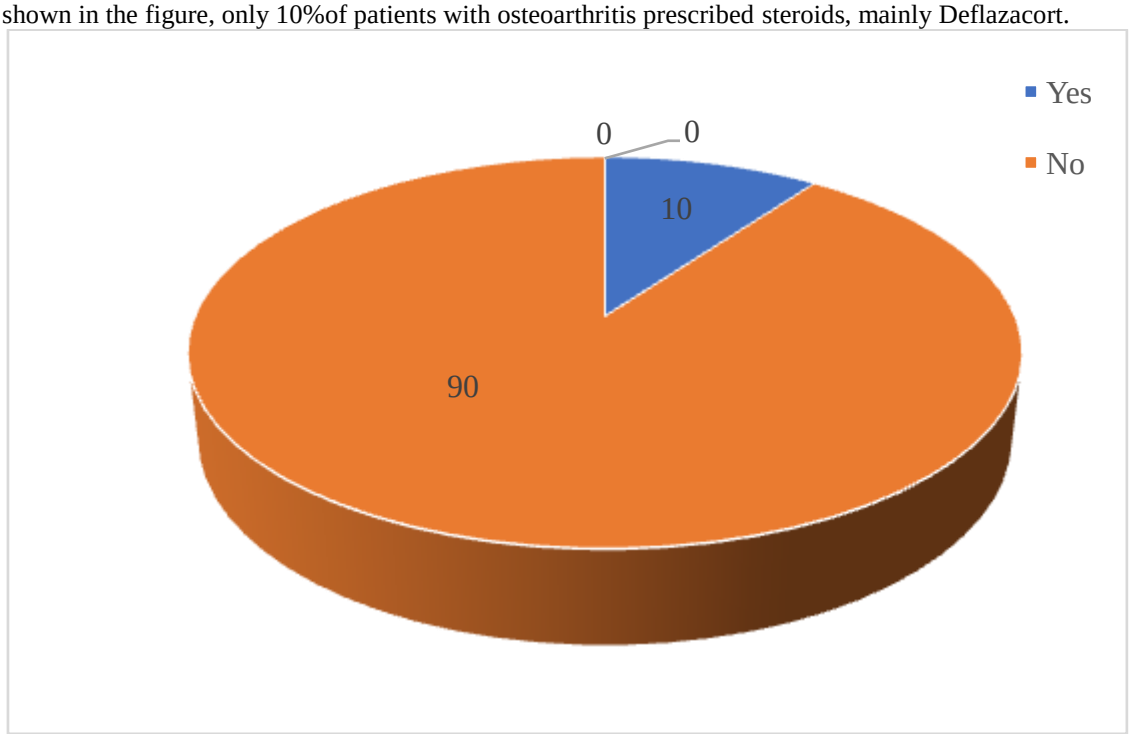

Figure 15 - Pattern of use of corticosteroids among study population

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2.6g Pattern of use of gastroprotectives among study population

From the figure below, majority of the patients were prescribed gastroprotective agents (94%). 65% prescribed PPI while 29% received H_2 blockers.

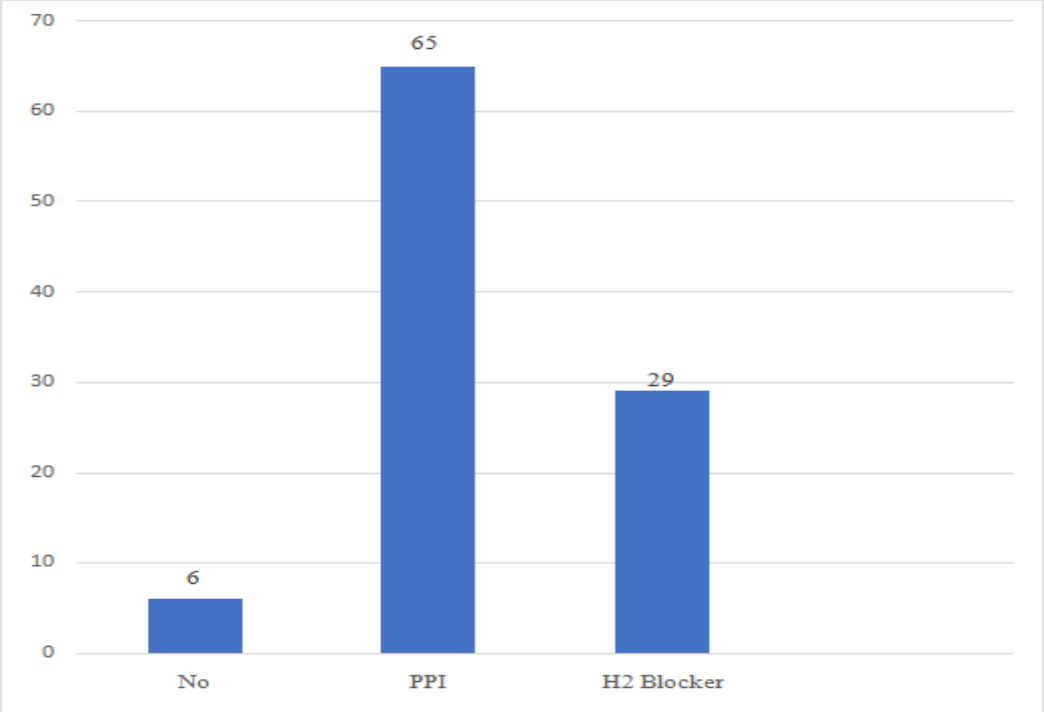

Figure 16: Pattern of use of gastroprotectives among study population

2.6h Pattern of use of GABA analogues among study population

From the figure below, only 31% were prescribed Gabapentin, Pregabalin and FDCs.

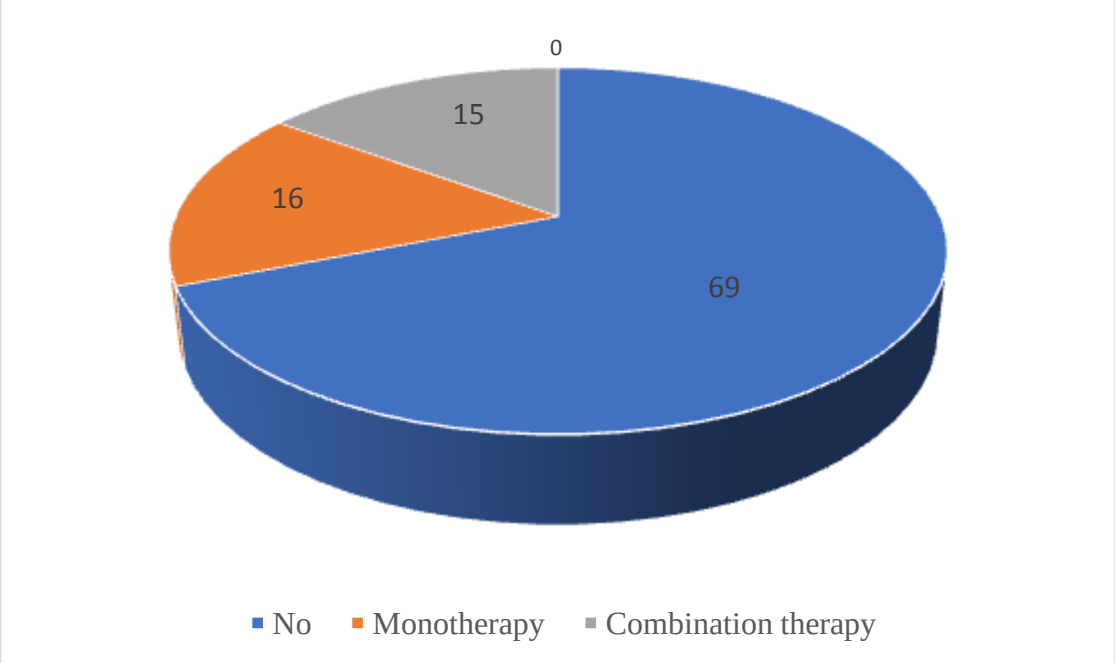

Figure 17 - Pattern of use of GABA analogues among study population

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2.6i Pattern of use of vitamins and minerals among study population

As shown in the figure, 57% patients with osteoarthritis were prescribed vitamins and minerals.

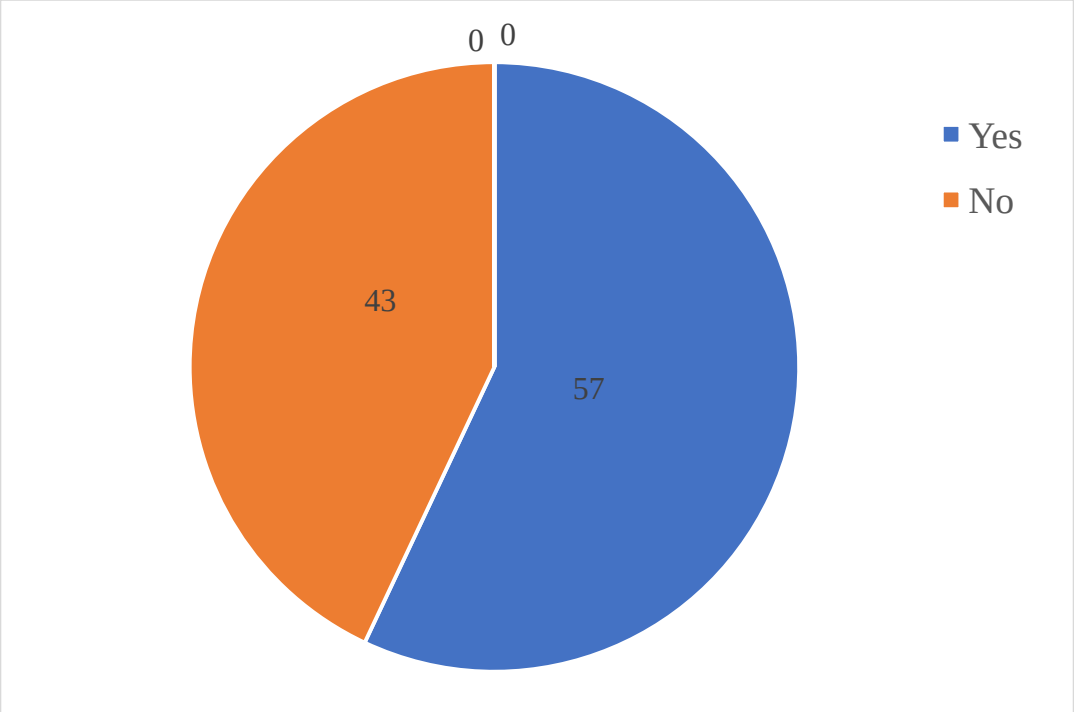

Figure18 - Pattern of use of vitamins and minerals among study population

III. DISCUSSION

Osteoarthritis is a localized degenerative disorder of multifactorial etiology. It is the major cause of pain and lower limb disability due to its predilection for lower extremity joints such as knee and hip. Risk factors includes age, joint trauma, genetic factors, gender, physically demanding occupations and inadequate physical activities.(23,24)

The study of prescribing patterns seeks to monitor, evaluate and if necessary, suggest modifications in the prescribing behaviour of medical practitioners to make medical care rational and cost effective.Rational use of drugs is very essential to minimize the adverse drug reactions and to improve quality of life of patients. Rational use of drugs implies that patients should receive medicines appropriate to their clinical needs, for an adequate period of time, at the lowest cost and in doses that meet their own individual requirements. Prescriptions hold a special importance in the rational use of drugs.(25)

The sample size of the current study was 100. In our study most of the patient belonged to the age group of 50-59 years. This is supported by the study conducted by Meenu Rani et.al.[86]The mean age was found to be 58.07±10.245 years.

In this study females showed a higher incidence of osteoarthritis than males, with 58% subjects being females compared to 42% males. This is supported by studies conducted by Ullal et.al.,Gupta R et al., Poornima B et al.and Haseeb.(27–29)Thus female sex is a major risk factor for OA and this could be due to their lack of physical activity.Besides, females in their menopausal period have low levels of estrogen, which is notprotective to the cartilage.

Majority of the patient in general were unemployed and unskilled. Housewives were also included in unemployed group.51% of patientswere overweight. 39% of patient had a previous history of trauma. This could be a reason for the development of osteoarthritis in the younger age group.

In this study 60% of patients had comorbidities, out of which a majority showed multiple comorbidities (32%). The most common comorbidity was dyslipidemiafollowed by hypertension. Whereas Gurung S et al observed that the most frequent co-morbid conditions were hypertension, diabetes, CAD, asthma and hypothyroidism.

In this study,the knee joint was the most commonly involved site (66%) followed by the hip

joint (21%). This is also supported by the study conducted by Gurung et al. It could be due to excessive use of squatting and cross-leg sitting positions.[89] The present study results are comparable with the studies conducted by Ansha Subramanian et al., Poornima B et al., and Venkatachalam J et al., wherein the knee was the most commonly involved joint in OA.(29,31)

Theaim of pharmacological treatment is to relieve the signs and symptoms,reduce the disease progression and to improve the quality of life in osteoarthritis patients.

In this study it was noted that most frequently prescribed drugswere NSAIDs. This is similar to studies done by Sahayam et al., Gupta et al;wherein NSAIDs were again the most commonlyprescribed drugs.(28) Among the NSAIDs, in this studyAceclofenac was the most commonly prescribed drugs (44%) followed by Diclofenac(30%). A similar finding was reported in a study conducted by AhmedMet. al. (32)

Selective COX-2 inhibitors were prescribed in 10% of cases while 68% of cases received purely Diclofenac astopical NSAIDs.There is growing evidence that topical and oral NSAIDs have equivalent efficacy; moreover, topical NSAIDs display better gastrointestinal safety than their systemic counterparts. This was supported by the study conducted by Gupta R et al.(28)

In this study only 20% of the patients were prescribed opioids (Tramadol). Among these 8% received Tramadol alone and 12% received combination of Tramadol + Paracetamol. This is supported by study conducted by Ansha Subramanian et al. wherein Tramadol combined with paracetamol was seen to be used in only 32 patients (12.5%).

Another observation in this study was that 10% of patientswere prescribedoral Deflazacort.

55% of patients received SYSADOA which included Glucosamine alone (18%), Diacerein alone (12%), FDCs of Glucosamine and Chondroitin, Diacerein and Chondroitin(25%) along with NSAIDs.The EULAR and OARSI recommendations have favoured the use of SYSADOA- Glucosamine sulphate, Diacerine especially in early OA. In the study by Olivier Bruyere et al,Chondroitin sulphate,Diacerine, Glucosaminesulphate have demonstrated reduction in pain and improvement in physical function, with very low toxicity. Despite these drugs being very safe with symptom modifying effects in OA, their under-prescription probably reflects the lack of faith in their clinical effectiveness and increased cost compared to NSAIDs.

Pregabalin was proved to be efficacious to treat neuropathic pain.In this study it was observed that 31% of patients received GABA analogues like Gabapentin and Pregabalin to relieve neuropathic pain.

Nutraceuticals refer to compounds or materials that can function as nutrition and exert a potential therapeutic effect, including the relief of pain, such as pain related to arthritis, of which osteoarthritis (OA) is the most common form.57% of patients in this study received nutritional supplements like Calcium, vitamin D_3, and B-complex.

Gastroprotective agents were commonly prescribed in OA patients to prevent non-selective NSAIDs induced gastrointestinal adverse effects. PPI like Pantoprazole and H_2 blockers like Ranitidine were the most commonly prescribed drugs. This observation is consistent with the findings, ofstudies done by Ullal et al. and Gupta R et al.(27,28)

Information from drug utilisation studies helps us to review the prescribing patterns, cost of treatment and their tolerability profile. This also helps to provide necessary feedback to the clinician and to evaluate the pattern of drug use with respect to the current recommendations or guidelines for the treatment of the condition.

IV. CONCLUSION

The current study was undertaken with the primary objective to determine the drug prescription pattern in patients with osteoarthritis attending the Rheumatology clinic under the Department of Internal Medicine, Govt medical college, Thrissur.

The following conclusions were derived from the study.

- Majority of the subjects were females
- Majority of the patientsbelonged to the age group 50-59 years
- The mean age of the study population was58.07$\pm$10.245
- Majority of the patients were overweight (51%)
- 60% of study population had comorbidities and among these 32% had multiple comorbidities
- Knee joint (66%) is most commonly affected
- Majority of the patient received multiple drug therapy
- NSAIDs werethe most commonly prescribed drug class among which Aceclofenac (44%) was the most widely prescribed drug
- Topical NSAIDs like Diclofenac gel were prescribed for 68% of study population

- SYSADOA were prescribed for 55% of study subjects along with NSAIDs
- GABA analogues were also prescribed for 31% of study participants
- Oral Deflazacort (10%) was also prescribed
- Opioids were prescribed for 20% of the study population
- Majority of the patients were prescribed gastroprotective agents (94%) with Pantoprazole being the commonest (44%)
- Majority of the patients were also prescribed nutritional supplements (57%)

This study underlines the importance of continuous prescription audit in a hospital, which will in turn provide regular feedback to the prescribers, thus significantly improving patient care.

Ethical Concern

My study did not include any interventions in patients, or on any other humans or animals.Ethical clearance was obtained from Institutional Ethics Committee and consent wasobtained from all patients.

Budget

All the expenses incurred in the study were met by the investigator.

Limitation of study

The study is confined to a small population attending the Rheumatology clinic under the Department of Internal Medicine of a tertiary care hospital which may not represent the general population

Any Conflict of interests expected: Nil

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