Journal of Pharmaceutical Research International



33(37A): 92-100, 2021; Article no.JPRI.70820 ISSN: 2456-9119 (Past name: British Journal of Pharmaceutical Research, Past ISSN: 2231-2919, NLM ID: 101631759)

A Prospective Observational Study on Prescription Pattern and Its Efficacy in the Management of Osteoarthritis at Multispecialty Teaching Care Hospital

Sarvajeet Khare¹, Trupal Rathod², Rajesh Hadia^{1*}, Sunil Baile¹, Nikhil Khambhati³, Sunil Kardani¹ and Dhaval Joshi²

¹Department of Pharmacy, Sumandeep Vidyapeeth Deemed to be University, Vadodara-391760, Gujarat, India. ²Department of Pharmacy Practice, Maliba Pharmacy College, Mahuva-Bardoli Road, Bardoli-394350, Gujarat, India. ³Department of Pharmacy Practice, SJM College of Pharmacy, Rajiv Gandhi University of Health Sciences, Chitradurga, Karnataka, India.

Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JPRI/2021/v33i37A31984 <u>Editor(s):</u> (1) Dr. Rafik Karaman, Al-Quds University, Palestine. <u>Reviewers:</u> (1) Sultan M. Alshahrani, King Khalid University, KSA. (2) Marc Prod'homme, Neuro Orthopedic Center, Switzerland. Complete Peer review History: <u>https://www.sdiarticle4.com/review-history/70820</u>

Original Research Article

Received 03 May 2021 Accepted 09 July 2021 Published 15 July 2021

ABSTRACT

Background: osteoarthritis is a severe clinical condition in elderly patients. Almost any bone can fracture as a result of the increased bone fragility of osteoarthritis.

Aim and Objective of study: The principle aim of drug utilization research is to facilitate the rational use of drugs in an individualized patient. To Study current prescription pattern and its efficacy to manage osteoarthritis.

Methodology: This study was a prospective observational study and conducted over a period of six month from October 2015 to March 2016. Patients diagnosed with arthritis with or without comorbidities were enrolled in the Study considering the inclusion and exclusion criteria. The main

^{*}Corresponding author: E-mail: docrajesh.hadia@gmail.com;

sources of data collection were OPD file and case sheets of patients.

Results: In this study 148 patients were enrolled, 105 (70.9%) female patients and 43 (29.1%) male patients were participated. Out of 148 study participants 60 (40.54%) patients from age group 51-65 years, followed by 54 (36.48%) patients from age group 36-50 years. In the study population 94 (63.51%) patient were suffering osteoarthritis of both knee, 29 (19.59%) patients were suffering osteoarthritis of right knee and 25 (16.89%) patients were having osteoarthritis of left knee. X-ray report were representing in study population, in 44 patient reports were shows degenerative change seen in both knee, 08 patient report were shows degenerative change seen in right knee. In our study out of 148 patients, 92 (62.16%) patients prescribed NSAIDs, 25 (16.89%) patients prescribed Analgesic, 05 (03.37%) patients were prescribed Opioid analgesic, 11 (07.43%) patients were prescribed supplements and 15 (10.13%) patients received other class of drugs. Among the study population 112 (75.67%) patients were received oral route of drugs and 36 (24.32%) Patients were prescribed topical preparation. The visual analogue scale has been categorized as follows 0-3 Mild pain, 4-7 Moderate pain and 8-10 severe pain. In visual analogue scale initially 16 patients were suffering mild pain, but after treatment it was 93 patients suffering mild pain. The facial pain scale has been categorized as follow 0 = very happy, no hurt, 2 = hurts just a little bit, 4 = hurts a little more 6 = hurts even more, 8 = hurts a whole lot, 10 = hurts as much as you can imagine. Among 148 study participants 14 patients were having final Facial pain score 0, 67 patients were having a final Facial pain score 2 and 3 patients having Initial Facial Pain score 2, 42 patients were having a final Facial pain score 4 and 42 patients having Initial Facial pain score 4, 19 patients were having a final Facial pain score 6 and 63 patients having Initial Facial pain score 6, 06 patients were having final Facial pain score 8 and 33 patients having Initial Facial pain score 8, 07 patients having Initial Facial score 10.

Conclusion: The principal aim of drug utilization research is to facilitate the rational use of drugs in an individualized patient. For the individual's patients, the rational use of a drug implies the prescription of the well documented drug at optimal dose, together with the correct information, at an affordable price.

Keywords: Efficacy; osteoarthritis; prescription pattern; facial pain score.

1. INTRODUCTION

The principle aim of drug utilization research is to facilitate the rational use of drugs in an patient. Osteoarthritis individualized is a condition which results in making bone so brittle that a fall or even mild stresses can result in fracture. Osteoarthritis prone areas in human bodies are in the knee, hip, wrist or spine [1]. Osteoarthritis is a severe clinical condition in elderly patients. 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. Eventually, if the cartilage wears down completely, bone will rub on bone. This disease has often been referred to as a wear and tear disease. But besides the breakdown of cartilage, osteoarthritis affects the entire joint. 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. Almost any bone can fracture as a result of the increased bone fragility of Osteoarthritis. These fractures are related to higher health care costs, physical

disability, decreased quality of life, more chance of mortality. Because the incidence of fracture increases with advancing age, measures to diagnose and prevent Osteoarthritis and its complications assume a major public health concern [2]. Facial pain scales consist of collection of line diagrams of faces with expressions of increasing distress. The facial expression has smiling face with no distress and as the facial expression become more stressful so it signifies to the more pain. The Visual Analog Scale (VAS), as well as nurses ratings based on behavior [3].

1.1 Need of Study

The prescription is written for osteoarthritis and in that mostly analgesics are the first choice to be prescribed and sometime it is rational and sometime irrational. The introduction of any other important remedy which will help to minimize the osteoarthritis problem must be included and studied. As per our finding from previous published literature we found that there were less number of study was conducted related to prescription pattern and management in combination for osteoarthritis so in order to fulfill this requirement and spread awareness among the community and health care sector and to come out with a fruitful result which will be a kind of sparkling light in lives of patients suffering or about to suffer from osteoarthritis. Our study is also helpful in knowing the prevalence of osteoarthritis unilaterally or bilaterally in accordance with the knee involvement.

2. METHODOLOGY

We performed a prospective observational study over a period of six month from October 2015 to March 2016. The main study site was orthopedic department at BMCH&RC. Patients diagnosed with arthritis with or without co-morbidities were enrolled in the Study considering the inclusion and exclusion criteria. The main source of data collection was Medical case sheet. The prescriptions of patients were analvzed demographic details of patient, drugs used in treatment and type of therapy in a specially designed data collection form. Statistical analysis was calculated by using descriptive statistics and no other methods were used.

3. RESULTS

In our study there is a sample size of 148 patients which fulfill our inclusion criteria. In this study 105 (70.9%) female patients and 43 (29.1%) male patients were participated. Out of 148 study participants 60 (40.54%) patients from age group 51-65 years, 54 (36.48%) patients from age group 36-50 years, 22 (14.86%) patients from age group 66-80 years, 09 (6.08%) patients from age group 20-35 years and 03 (2.02%) patients from age group 81-95 years. The results are shown for Age and gender distribution is graphically represented in Table 1 and Fig. 1.

In the study population 94 (63.51%) patient were suffering osteoarthritis of both knee, 29 (19.59%) patients were suffering osteoarthritis of right knee and 25 (16.89%) patients were having osteoarthritis of left knee are demonstrated in Table 2 and graphically illustrated in Fig. 2.

X-ray report of 44 patients results in degenerative changes seen in knee bilaterally, 08 patient report were shows degenerative change seen in right knee, 18 patients report were shows degenerative change seen in left knee, 16 patient report were shows early degenerative change seen in both knee, 04

patient were shows early degenerative change seen in right knee, 05 patients report shows early degenerative change seen in left knee, 10 patient were shows gross degenerative changes seen in knees bilaterally, 04 patient were shows gross degenerative changes seen in right knee, 03 patients were shows gross degenerative changes seen in left knees knee, 23 patient report shows decreases medial compartment space of knee bilaterally, 06 patients report represents decreases medial compartment space of right knee and 07 patients report represents decreases medial compartment space of left knee.

Considering medical prescriptions, 92 (62.16%) patients received Non-steroidal anti-inflammatory drugs (NSAIDs), 25 (16.89%) patients prescribed Analgesic, 05 (03.37%) patients were prescribed Opioid analgesic, 11 (07.43%) patients were prescribed supplements and 15 (10.13%) patients received other class of drugs. Distribution of patients based on Treatment is represented in Table 3. Among the study subjects common prescribing pattern were Piroxicam, Aceclofenac, Indomethacin, Etoricoxib and Oxaceprol patients were received as a monotherapy. Aceclofenac + Paracetamol, Acetaminophen + Tramadol and Tramadol + Diclofenac patients were received as dual Aceclofenac + Paracetamol therapy. Sarratiopeptidase and Aceclofenac Paracetamol + Thiocholchicoside patients were received as triple therapy.

Among the study population 112 (75.67%) patients received oral route of drugs and 36 (24.32%) Patients prescribed topical preparation as represented in Table 4. In our study 95 (64.18%) patients received monotherapy, 40 (27.02%) Patients received dual therapy and 13 (8.7%) patients received triple drug therapy respectively.

The total number of patients was evaluated for their pain at the time of admission as well as after receiving drug therapy by using pain scale like visual analogue scale and facial pain scale.

3.1 Visual Analogue Scale

The visual analogue scale has been categorized as follows 0-3 Mild pain, 4-7 Moderate pain and 8-10 severe pain. In visual analogue scale initially 16 patients were suffering mild pain, but after treatment it was 93 patients suffering mild pain. Initial stage 99 patient were suffering moderate pain but after the treatment it was reduced to 49 patients suffering moderate pain. Finally in initial stage 33 patients were suffering severe pain but after receiving treatment it was reduced to 06 patients. The detailed results are shown in Table 5 and Fig. 3.

3.2 Facial Pain Scale

The facial pain scale has been categorized as follow 0 = very happy, no hurt, 2 = hurts just a little bit, 4 = hurts a little more 6 = hurts even more, 8 = hurts a whole lot, 10 = hurts as much as you can imagine. Among 148 study participants 14 patients were having final Facial pain score 0, 67 patients were having a final Facial pain score 2 and 3 patients having Initial Facial Pain score 2, 42 patients were having a final Facial pain score 4 and 42 patients having Initial Facial pain score 4, 19 patients were having a final Facial pain score 6 and 63 patients having Initial Facial pain score 6, 06 patients were having final Facial pain score 8 and 33 patients having Initial Facial pain score 8, 07 patients having Initial Facial score 10. This has been shown in Table 6 and graphically represented in Fig. 4.

At the baseline Visual Analogue Scale evaluation has represents 33 patients having a severe pain, 99 patients having a moderate pain and 16 patients having a mild pain. The follow up scored represents 06 patients having a severe pain, 49 patients having a moderate and 93 patients having a mild pain. This has shown a significant reduction in pain. Out of 148 patients 11 patients reported that they did not experience any pain after using the medications. This has been represented in graphically represented in Fig. 5.

While using Facial Pain Scale out of 148 patients initially at baseline 40 patient were reported severe pain but it was reduced to 6 patients. Initially 105 patients were reported moderate pain but it was reduced to 61 patients. Only 2 patients were reported initially mild pain but after the treatment 67 patient reported mild pain and 14 patients also reported as there is no pain.

Table. I Genuel uisti ibution according to ag	Table.	1	Gender	distribution	according	to	age
---	--------	---	--------	--------------	-----------	----	-----

Age groups (Years)	Number of Male Participants (%) 43 (29.1)	Number Female Participants (%) 105 (70.9)	Total (%) 148 (100)
20-35	02	07	09 (6.08)
36-50	14	40	54 (36.48)
51-65	18	42	60 (40.54)
66-80	08	14	22 (14.86)
81-95	01	02	03 (2.02)



Fig. 1. Gender distribution according to age

Table 2. Distribution of patient according to type of osteoarthritis

Type of	Osteoarthritis of both	Osteoarthritis of Right	Osteoarthritis of left
Osteoarthritis	knees	knees	knees
Male	24	12	07
Female	70	17	18
Total	94 (63.51%)	29 (19.59%)	25 (16.89%)



Fig. 2. Distribution of patient according to type of osteoarthritis

Table 3. Distribution of patients based on Class of drugs prescribed

SI No	Class of Drug Prescribed	Number of Patient (%)
1	NSAIDs	92 (62.16)
2	Analgesics	25 (16.89)
3	Opioid analgesic	05 (03.37)
4	Supplements	11 (07.43)
5	Others	15 (10.13)

Table 4. Distribution of patients based on Type of Route of Drug Administration

Route of Drug Administration	Number of Patient (%)
Oral	112 (75.67)
Topical	36 (24.32)

Visual Analogue Pain Score	Number of Patient Initial score at Time of Admission (%)	Number of Patient Final score at time of After receiving drug therapy (%)
Score 0	00 (00)	11 (7.43)
Score 1	00 (00)	13 (8.78)
Score 2	01 (0.67)	29 (19.59)
Score 3	15 (10.13)	40 (27.02)
Score 4	16 (10.81)	19 (12.83)
Score 5	31 (20.94)	07 (4.72)
Score 6	32 (21.62)	10 (6.75)
Score 7	20 (13.51)	13 (8.78)
Score 8	20 (13.51)	02 (1.35)
Score 9	07 (4.72)	02 (1.35)
Score 10	06 (4.05)	02 (1.35)

Table 5. Distribution based on Visual Analogue Scale



Fig. 3. Distribution based on Visual Analogue Scale

Visual Analogue Pain Score	Number of Patient Initial score at Time of Admission (%)	Number of Patient Final score at time of After receiving drug therapy (%)
Score 0	00 (00)	14 (9.45)
Score 2	03 (2.02)	67 (45.27)
Score 4	42 (28.37)	42 (28.37)
Score 6	63 (42.56)	19 (12.83)
Score 8	33 (22.29)	06 (4.05)
Score 10	07 (4.72)	00 (00)

Table 6. Distribution based on Facial Pain Scale



Fig. 4. Distribution based on Facial Pain Scale







Fig. 6. Efficacy of medicine by pain measurement as per Facial Pain Scale

4. DISCUSSION

According to Stevens-Lapsley JE and Kohrt WM, Osteoarthritis (OA) is the leading cause of disability in USA. Women have a higher prevalence of OA than men, but the underlying causes for the increased susceptibility of women to OA are not fully understood. Obesity clearly increases risk for OA, Moderate levels of physical activity do not appear to increase the incidence or progression of OA and may even have a weak protective effect. In our study we also have the same kind of prevalence out of 148 total sample sizes of male and female, 105 females suffer from osteoarthritis. So, this study also shares a spotlight towards the gender bases osteoarthritis condition [4].

According to Rannou F, Pelletier JP, Martel-Topical non-steroidal Pelletier anti-.1 inflammatory drugs (NSAIDs) are as an early treatment option for the symptomatic management of knee and hand osteoarthritis (OA), and may be used ahead of oral NSAIDs due to their maximum efficacy. The European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ESCEO) treatment algorithm recommends topical NSAIDs for knee OA in addition to the pharmacological background of symptomatic slow-acting drugs for osteoarthritis (SYSADOAs) and due to these particular effects, our patients ,92 out of 148 were given NSAIDS in their treatments and they showed a positive effect and their preexisting condition were improved [5].

According to Derry S, there is good evidence that some formulations of topical diclofenac and ketoprofen are useful in acute pain conditions such as sprains or strains, with low (good) NNT (number needed to treat) values. There is a strong message that the exact formulation used is critically important in acute conditions, and that might also apply to other pain conditions. In chronic musculoskeletal conditions with assessments over 6 to 12 weeks, topical diclofenac and ketoprofen had limited efficacy in hand and knee osteoarthritis, as did topical highconcentration capsaicin in post neuralgia. So, in our study also 25 patients were prescribing analgesics in order to control the pain condition and they are relieved from pain [6].

Among the study subjects common prescribing pattern were Piroxicam, Aceclofenac, Indomethacin, Etoricoxib and Oxaceprol patients were received as a monotherapy. Aceclofenac + Paracetamol, Acetaminophen + Tramadol and Tramadol + Diclofenac patients were received as dual therapy. Aceclofenac + Paracetamol + Sarratiopeptidase and Aceclofenac Paracetamol + Thiocholchicoside patients were received as triple therapy. The combination therapy plays a major role in osteoarthritis because the monotherapy, dual therapy and triple therapy is an effective treatment in mild, moderate, severe category of osteoarthritis. Current guidelines on the management of hip and knee osteoarthritis (OA) do not compare safety of treatment modalities. We therefore systematically reviewed 20 studies investigating mortality and serious complications of both medical and surgical treatments for hip and knee OA using PubMed, Scopus, Web of Knowledge and Google Scholar. Mortality was the highest for naproxen (hazard ratio (HR) = 3 (1.9, 4.6)) and lowest for total hip replacement (relative risk (RR) = 0.7 (0.7, 0.7)). Highest gastrointestinal complications were reported for diclofenac (odds ratio (OR) = 4.77 (3.94, 5.76)) and lowest for total knee replacement (HR = 0.6 (0.49, 0.75)). Ibuprofen had the highest renal complications (OR = 2.32 (1.45, 3.71)), whereas celecoxib had the highest cardiovascular risk (OR = 2.26 (1, 5.1)) and lowest was for tramadol (RR = 1.1 (0.87, 1.4)). Results show that medical management of hip and knee OA, particularly with non-steroidal anti-inflammatory drugs, may carry higher mortality compared to surgery. Careful consideration should be given to medical management taking into account known comorbidities. Aweid, O et al. 2,127 patients were included: mean age 65.4 (SD 9.1) years and 59.2% female. Currently used treatments for knee OA were: 57.6% exercise and/or physiotherapy, 61.1% NSAIDs, and 29.8% opioid analgesics. In multivariable regression, controlling for potential confounders, comorbid hypertension (RR 1.18, 95% CI 1.02-1.37), gastrointestinal disease (RR 1.31, 95% CI 1.07-1.60), depressed mood (RR 1.25, 95% CI 1.05-1.48) and a higher number of troublesome joints (RR 1.04 per joint, 95% CI 1.00-1.09) were associated with opioid use, with no association found with having ever used recommended nonopioid pharmacological or non-pharmacological treatments [7].

According to King LK et al. the mean age and sex were similar across years (77 years and 69% women, respectively). There was a significant increase in opioid prescribing between 2003 and 2009, with 31% of patients receiving opioids in 2003, 39% in 2006, and 40% in 2009 (odds ratio

[OR] 1.5, 95% confidence interval [95% CI] 1.1-2.0 for 2006 and 2009 compared with 2003). Independent correlates of opioid use across time periods included female sex (OR 1.5, 95% CI 1.2-2.0), functional limitation (OR 2.1, 95% CI 1.6-2.7), poor self-reported health status (OR 1.6, 95% CI 1.2-2.0), chronic obstructive pulmonary disease (OR 1.4, 95% CI 1.0-1.8), and musculoskeletal disease besides OA (OR 1.9, 95% CI 1.2-2.8) [8].

Moderate quality evidence indicates that compared to placebo, tramadol alone or in combination with acetaminophen probably has no important benefit on mean pain or function in people with osteoarthritis, although slightly more people in the tramadol group report an important improvement (defined as 20% or more). Moderate quality evidence shows that adverse events probably cause substantially more participants to stop taking tramadol. The increase in serious adverse events with tramadol is less certain, due to the small number of events according to Toupin April K et al. [9].

5. CONCLUSION

The principle objective of drug utilization research is to facilitate the rational use of drugs in an individualized patient. For the individual's patients, the rational use of a drug implies the prescription of the well documented drug at optimal dose, together with the correct information, at correct price. Without knowledge of how drugs are being prescribed and used, it is difficult to initiate the discussion on rational use of drug and also, we cannot suggest measures to improve prescribing habits. Even the efficacy of drugs used in pain management can be evaluated by these studies. So, the purpose of the study was to analyze the current prescribing pattern and their efficacy in pain management in osteoarthritis patient.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

ETHICAL APPROVAL AND CONSENT

This study obtained approval from Institutional Human Ethical Committee of the S.J.M College of Pharmacy, Chitradurga, Karnataka. (SJMCP/IEC-543K/ 2015-16). Informed consent was taken from patient at the time of enrolment in to the study.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

- Mayoclinic; 2019. [Online]. Available:https://www.mayoclinic.org/disea sesconditions/osteoporosis/symptomcauses/syc-20351968. [Last accessed on 23 April, 2019].
- Srivastava M, Deal C. Osteoporosis in elderly: Prevention and treatment. Clin Geriatr Med. 2002;18(3):529-55.
- Charles J. Coté, Jerrold Lerman and I. David Todres. A practice of anesthesia for infants and children. Fourth Edition. 2009:22-27.
- Stevens-Lapsley, Jennifer E, and Wendy M Kohrt. Osteoarthritis in women: Effects of estrogen, obesity and physical activity. Women's health (London, England). 2010;6(4):601-15. DOI:10.2217/whe.10.38.
- Rannou F, Pelletier JP, Martel-Pelletier J. Efficacy and safety of topical NSAIDs in the management of osteoarthritis: Evidence from real-life setting trials and surveys. Semin Arthritis Rheum. 2016;45(4):S18-21. DOI:10.1016/j.semarthrit.2015.11.007. Epub 2015 Dec 2. PMID: 26806189.

 Derry S, Wiffen PJ, Kalso EA, Bell RF, Aldington D, Phillips T, Gaskell H, Moore RA. Topical analgesics for acute and chronic pain in adults - an overview of Cochrane Reviews. Cochrane Database Syst Rev. 2017;5(5):CD008609. DOI: 10.1002/14651858.CD008609.pub2. PMID: 28497473; PMCID: PMC6481750.

 Aweid O, Haider Z, Saed A, Kalairajah Y. Treatment modalities for hip and knee osteoarthritis: A systematic review of safety. Journal of Orthopaedic Surgery, 2018;26(3).

Available:https://doi.org/10.1177/23094990 18808669.

Khare et al.; JPRI, 33(37A): 92-100, 2021; Article no.JPRI.70820

- King LK, Marshall DA, Jones CA, Woodhouse LJ, Ravi B, Faris PD, Hawker GA; BEST-Knee Team. Are medical comorbidities contributing to the use of opioid analgesics in patients with knee osteoarthritis? Osteoarthritis Cartilage. 2020;28(8):1030-1037. DOI:10.1016/j.joca.2020.04.012.
- Toupin April K, Bisaillon J, Welch V, Maxwell LJ, Jüni P, Rutjes AWS, Husni ME, Vincent J, El Hindi T, Wells GA, Tugwell P. Tramadol for osteoarthritis. Cochra0000000ne Database of Systematic Reviews. 2019;5:CD005522. DOI:10.1002/14651858.CD005522.pub3. Accessed 24 June 2021.

© 2021 Khare et al.; This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/4.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Peer-review history: The peer review history for this paper can be accessed here: https://www.sdiarticle4.com/review-history/70820