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DRUG UTILIZATION EVALUATION AND PRICE VARIABILITY STUDY OF NON-STEROIDAL ANTI- INFLAMMATORY DRUGS IN THE ORTHOPAEDIC DEPARTMENT OF A TERTIARY CARE HOSPITAL

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Abstract

The study aims to evaluate the drug utilization pattern of NSAIDs in orthopaedic in-patient department of a tertiary care hospital, Dakshina Kannada district, Karnataka. A prospective observational study was carried out for a period of eight months. The drug utilization pattern of NSAIDs was analyzed by collecting the drug therapy details of the patients. The data were analyzed using descriptive statistics. A total number of 190 patients were included in the study, and among them, the majority of the patients were males (65.3%). Most of the patients were in the age group of 40-49 years (29.5%). The majority of the patients were prescribed NSAIDs for fracture (36.3%). In this study, fixed-dose combinations (79%) of NSAIDs were more preferred than single-drug therapy (21%). Gastroprotective agents (97.89%) were the most commonly co-prescribed drug with NSAIDs. A total of 802 drugs, 16.22% of drugs was prescribed in generic name whereas, 39.65% were prescribed from NLEM-2015 and 24.81% from the WHO model list of essential medicine-March 2017. Diclofenac sodium (50mg, tab) showed a maximum percentage price variation of 581.96 while Etoricoxib+Thiocolchicoside (60/4 mg tab) showed a minimum percentage price variation of 3.42. The usage pattern of NSAIDs were analyzed and prescriptions were assessed according to WHO prescribing indicators

***Keywords*:** Non-steroidal anti-inflammatory drugs, Drug utilization, price variation.

Introduction

Non-steroidal anti-inflammatory drugs (NSAIDs) are a class of drugs with proven characteristics as an analgesic, anti-inflammatory, and antipyretic activity and are commonly prescribed worldwide. Periodical evaluation of drug utilization pattern modifies the prescribing trends of NSAIDs, improves the therapeutic benefits and minimizes the adverse effects (Jyothi *et al*., 2013). There are mainly two types of cyclooxygenase enzymes, COX-1 and COX-2. The majority of the traditional NSAIDs are nonselective inhibitors of both COX-1 and COX-2 which vary in the degree of COX inhibition. It reduces inflammation as well as blocks the protective role of COX-1, thus giving rise to GI side effects. Selective COX-2 inhibitors have more than 50-fold selectivity for COX-2 and they are potent and safe anti-inflammatory drugs with lesser GI side effects. Preferential COX-2 inhibitors (meloxicam, etodolac etc) have 10-20 fold COX-2 selectivity (Sadhotra *et al*., 2016). A new COX isozyme (COX-3) has been recently identified, but its action is not yet known. Mainly the use of NSAID is empirical in inflammatory conditions and they provide only symptomatic relief without considering the disease process (Sanji *et al*., 2010). Recent studies have shown that NSAIDs are the most commonly used and abused drug in the world. A variety of NSAIDs combinations with different formulations are available in the Indian market which created a lot of problems for the physicians to decide the drug choice among the individual patients (Gupta *et al*., 2005). The World Health Organization (WHO) defines drug utilization research (DUR) as "the marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences (Raut *et al*., 2013)." The ultimate goal of DUR is to evaluate whether drug treatment is rational or not. The main causes of irrational drug use are self-medication, inappropriate use of antibiotics, polypharmacy, overuse of injections, and irrational prescriptions. The World Health Organization (WHO) formulated a set of indicators and appropriate methodology to evaluate the drug prescribing patterns and dispensing behavior in various healthcare setups (Al-Jabri *et al*., 2019; Gouda *et al*., 2019; D'souza *et al*., 2019 and Voora *et al*., 2020). Periodical evaluation of drug utilization patterns improves the prescribing trends of NSAIDs, promotes the therapeutic benefits and reduces the adverse effects. DUE studies suggest modifications in prescribing behaviors of the medical practitioners to make rational prescription of drugs which is cost-effective.

Material and Methods

Study Design

The prospective observational study design was adopted for this study. The data was collected from September 2017 to April 2018 at Orthopaedic inpatient department of a tertiary care teaching hospital located in Dakshina Kannada district, Karnataka. The Institutional Ethical Committee permission was taken to conduct this study (IEC approval no.: NGSMIPS/IEC/04/2017-18).

Inclusion and Exclusion Criteria

Patients who received NSAIDs in orthopaedics ward during the study period irrespective of sex, diagnosis, and treatment were enrolled in the study. Prescriptions of patients attending orthopedic OPD and those who were admitted to other inpatient departments were excluded from the study. The patients who were absconded or discharged against medical advice were excluded from the study.

Study procedure

A total of 190 patients were enrolled during the study. Demographic data comprised age, sex, and date of admission, height, weight. The clinical data included diagnosis, name of NSAIDs, route of administration, duration of treatment, any adverse event with NSAIDS(if any), co-prescribed drugs, and duration of hospital stay were recorded. These data were documented in a pre-designed case record form. NSAIDs prescribed by Physicians of the orthopaedic department of this hospital were considered in this study.

Prescription assessment according to WHO prescribing indicators:

The prescriptions of NSAIDs were analyzed by using WHO prescribing indicators included were: (Al-Jabri *et al*., 2019 and WHO 1993).

- The average number of drugs per encounter
- Percentage of drugs prescribed by generic name
- Percentage of encounters with an antibiotic prescribed
- Percentage of encounters with an injection prescribed
- Percentage of drugs prescribed from essential drug list

Price variation Analysis of different brands of NSAIDs

- The hospital pharmacy department and the Current Index of Medical Specialties (October 2017- January 2018) were used for the price variation analysis of different brands of NSAIDs.
- Cost per tablet of a particular drug of various dosage forms and strengths, manufactured by different companies were compared.
- Drugs with only one brand available were excluded.
- Cost differences between the minimum and maximum costs of similar drugs were calculated.
- Percentage price variations for all brands of NSAIDs were calculated (Patel *et al*., 2009).

Statistical analysis

Data were analyzed using descriptive statistics. The frequency with percentage was used to summarize the demographics of the patient, indications, prescribing pattern of NSAIDs, type of therapy, and route of administration. Mean and standard deviation were used to derive age whereas; median and standard deviation were used to summarize the length of hospital stay. Analysis of the data was carried out by using Statistical Package for Social Science (SPSS) 16.0 for windows.

Results

Demographic details of the enrolled study subjects

Out of the total 190 study subjects, 124 were males, which constituted 65.3% and 66 were females which constituted 34.7%. According to the age-wise distribution of the study subjects, the majority were in the age group of 40-49 years (29.5%), followed by 30-39 years (23.7%). The mean age of the study population was $40.9^{\pm}12.8$ years. The age-wise distributions of patients are summarized in Table 1.

Distribution of patients according to their indications

In this study, most of the patients were prescribed with NSAIDs for fracture (36.3%) followed by Intra-Vertebral Disc Prolapse (IVDP) (26.3%). The indications for prescribing NSAIDs are summarized in Table 2.

Association of surgeries done with the indications

Out of the study population, 105 patients underwent different surgeries. In this study, implant removal (10), knee injury (8) carpal tunnel syndrome (2), and Chondromyxoid fibroma (1) underwent surgery. The majority of the patients were admitted with fracture (69), out of which 67 underwent surgery. The association of surgeries done with the indication is illustrated in Figure 1.

Distribution of class of drug

In this study, non-selective COX inhibitors (98%) were prescribed in the majority of the patients, and only 2% of the patients were prescribed with selective COX-2 inhibitors.

Prescribing pattern of NSAIDs

Types of therapy

In this study, 79% of patients were prescribed with fixed-dose combinations (FDCs) of NSAIDs and 21% of patients with single-drug therapy.

Single drug therapy of NSAIDs used

In this study, diclofenac was the most commonly used NSAID in both surgical (60%) and non-surgical (20%) patients whereas; aceclofenac (10%), indomethacin (5%) and etoricoxib (5%) were prescribed only in non-surgical patients.

Distribution of fixed-dose combinations of NSAIDs used

A total of 150 fixed-dose combinations of NSAIDs were prescribed in the study population, out of which 81 FDCs (54%) were prescribed in surgical patients and 69 FDCs (46%) in non-surgical patients. Diclofenac+Trypsin Chymotrypsin (54.3%) were the commonly prescribed FDC in the surgical patients, followed by Diclofenac +Trypsin+ Bromelain+Rutoside (22.2%) and other FDCs. In the non-surgical patients, Diclofenac +Paracetamol +Chlorzoxazone (43.5%) were most commonly prescribed followed by Diclofenac + Metaxolone (15.9%), Aceclofenac + Paracetamol + Chlorzoxazone (13%) and other FDCs. These data are illustrated in Tables 3 and 4 respectively.

Topical & parental administration of NSAIDs used

Topical NSAIDs were prescribed only in non-surgical patients. Out of 85 non-surgical patients, 31 were prescribed with topical preparation. Diclofenac+Methyl salicylate Menthol (18.82%) was the most commonly used topical preparation. In this study, only diclofenac injection was used in both surgical (65.71%) and non-surgical (4.71%) patients.

Distribution pattern of concomitant medications prescribed

Out of the total study population (190), 186 (97.89%) patients were prescribed with gastroprotective agents, out of which proton pump inhibitors (74.2%) and H2-Receptor antagonist (25.8%) were involved. Pantoprazole was the most commonly used PPI in both surgical (84.6%) and non-surgical (81.7%) patients. In surgical cases, antibiotics were

given in all patients, whereas, in non-surgical cases, multivitamins (37.6%) were mainly used.

Distribution of route of administration

A total of 294 NSAIDs were prescribed in the study population, out of which 65% were given orally followed by parenteral (25%) and topical (10%).

Prescription assessment according to WHO prescribing indicators

Among 190 patients who received a total of 802 drugs, 16.22% of drugs were prescribed in the generic name, followed by 39.65% were prescribed from NLEM-2015 and 24.81% from the WHO model list of essential medicine-March 2017. Out of 190 patients, 65.79% were prescribed with injection, 57.36% were prescribed with antibiotics and the average number of drugs per prescription was 4.22. The data are summarized in Table 5.

Price variation of different brands of NSAIDs

Among the various brands of NSAIDs available in the hospital pharmacy department, Diclofenac sodium (50mg, tab) exhibited a maximum percentage price variation of 581.96 while Etoricoxib+ Thiocolchicoside (60/4 mg tab) exhibited minimum percentage price variation of 3.42. The price variations of different brands of NSAIDs are summarized in Table 6.

Discussion

NSAIDs are the most effective class of medication used in the treatment of various indications where pain and inflammation are present. The study of utilization pattern of NSAIDs is a component of the medical audit, which seeks appropriate monitoring and assessment to achieve rational medical care. In this study, the percentage of male patients (65.3%) was more when compared to female patients (34.7%); these results are similar to the other studies (Raut *et al*., 2013; Singh *et al*., 2014 and Bhat *et al*., 2013), where they reported that males were more than the females. Majority of the patients admitted to the inpatient department of orthopaedics falls in the age group of 40-49 years (29.5%), this result is similar to another study (Bhat *et al*., 2013), where they reported that most of their patients were in the age group of 41-50 years (24.8%). In the present study, the majority of the patients were prescribed with NSAIDs for fracture 69(36.3%), which is similar to other studies (Agarwal *et al*., 2018) which reports; fracture was the most common problem for hospitalization in the orthopaedics department. On categorizing the NSAIDs prescriptions, it was observed that fixed-dose combinations of NSAIDs were most commonly used than single-drug therapy. These results are similar to the other studies conducted (Mudhaliar *et al*., 2016; Jyothi *et al*., 2013 and Alama *et al*., 2013).

In this study, Diclofenac+Trypsin Chymotrypsin (54.3%) was the most commonly prescribed FDC in surgical patients and Diclofenac + Paracetamol + Chlorzoxazone (43.5%) in non-surgical patients. The present study shows that diclofenac injection was most commonly used in surgical patients than non-surgical patients. These observations are similar to a study conducted by other authors (Rajarathna *et al*., 2014). The reason behind this is the superior efficacy to control the post-operative pain parenterally in the initial post-operative period. In the current study, non-selective COX inhibitors (98%) were prescribed in the majority of the patients whereas, only 2% of the patients were prescribed with selective COX-2 inhibitors. This observation is similar to the other studies conducted (Raut *et al*., 2013 and Singh *et al*., 2014). This is because selective COX-2 inhibitors increase the risk of cardiac adverse effects. The study showed that different classes of concomitant medication were prescribed along with the NSAIDs, out of which gastroprotective agents (97.9%) were most commonly prescribed. Pantoprazole was the most commonly prescribed proton pump inhibitor in both surgical and non-surgical patients and only ranitidine was prescribed from the H_2-receptor antagonists (Bhat *et al*., 2013 and Antappan *et al*., 2017). This is because more sustained acid suppressions produced by proton pump inhibitors when compared to H_2-receptor antagonists. A total of 294 NSAIDs were prescribed to the study population, out of which 65% were prescribed orally (Jyothi *et al*., 2013 and Sadhotra *et al*., 2016). In the present study, the average number of drugs prescribed per prescription was 4.22 (Rajarathna *et al*., 2014). It was higher than the standard (< 2) (WHO 1993). These studies were conducted only in inpatients. The percentage of drugs prescribed by generic name was 12.22%, which is very less when compared to the standard (WHO, 1993). This result is similar to the study conducted by another author (Rajarathna *et al*., 2014). Drugs prescribed in the generic name helps to improve the rational use of a drug, to reduce the cost of therapy and to avoid the dispensing errors.

The percentage of drugs prescribed from NLEM-2015 was 39.65 %, and from the WHO model list of essential medicines – March 2017 was 24.81%, which is very less when compared to the standard recommended value (100%). These results are contrary to the other studies conducted (Rajarathna *et al*., 2014 and Singh *et al*., 2014). The percentage of injection prescribed was 65.79%, much higher than the standard (< 20%). Most of the injections were prescribed in the surgical patients for control of postoperative pain. The percentage of antibiotics prescribed was 57.36%, which is higher than the standard recommended value of >30% (WHO 1993). This is because most of the antibiotics were prescribed in surgical patients. This study reports that out of various brands of NSAIDs available in our hospital pharmacy department, diclofenac sodium (50mg, tab) showed a maximum percentage price variation of 581.96 while etoricoxib+thiocolchicoside (60/4 mg tab) showed minimum percentage price variation of 3.42 (Gupta *et al*., 2005). Where aceclofenac+paracetamol (100/500mg tablet) showed the highest price variation 3400 and the average percentage variation in cost was 107.4 because in their study, price variation was done for different brands of NSAIDs available in the Indian market. A wide variation in the prices of the different brands of NSAIDs was seen which will increase the economic burden of the patients. Hence, importance should be given for the prescription of the generic drugs

Conclusion

Drugs prescribed in the generic name helps to improve the rational use of the drug, to reduce the cost of therapy, and to avoid the dispensing errors. This study showed wide price variations of NSAIDs. Hence, there is a need to produce uniformity in prices thereby, decreasing the economic burden on the patients. Thus, pharmacists and other health care professionals should work together to promote the rational use of NSAIDs and minimize the cost of therapy.

Table 1: Age-wise distribution of patients

Age group (years)	Number of patients	Percentage (%)
18-29	41	21.6
30-39	45	23.7
40-49	56	29.5
50-59	36	18.9
60-69	9	4.7
≥70	3	1.6

Table 2 : Indications for prescribing NSAIDs

Indications	Number of patients	Percentage (%)
Fracture	69	36.3
Intra-Vertebral Disc Prolapse	50	26.3
Osteoarthritis	10	5.3
Lumbar spondylosis	14	7.4
Implant removal	10	5.3
Knee injury	8	4.2
Acute lumbar Strain	6	3.2
Spondylolisthesis	5	2.6
Cervical spondylosis	4	2.1
Joint dislocation	3	1.6
Cellulitis	2	1.1
Rheumatoid arthritis	2	1.1
Carpal tunnel syndrome	2	1.1
Chondromyxoid fibroma	1	0.5
Bone tuberculosis	1	0.5
Impingement Syndrome	1	0.5
Osteoporosis	1	0.5
Synovitis	1	0.5

Table 3 : Distribution of FDC in surgical patients

Drug name	Frequency	Percentage (%)
Diclofenac+Paracetamol	10	12.3
Aceclofenac+Paracetamol	7	8.6
Diclofenac+ Trypsin Chymotrypsin	44	54.3
Diclofenac+Trypsin+Bromolein+Rutoside	18	22.2
Ibuprofen+Paracetamol	2	2.5

Table 4 : Distribution of FDC in Non-surgical patients

Drug name	Frequency	Percentage (%)
Diclofenac+Paracetamol	5	7.2
Diclofenac+Metaxolone	11	15.9
Aceclofenac+Paracetamol	3	4.3
Aceclofenac+Paracetamol + Chlorzoxazone	9	13.0
Diclofenac +Paracetamol +Chlorzoxazone	30	43.5
Etrocoxib+Thiocolchicoside	2	2.9
Aceclofenac+Tizanidine	4	5.8
Ibuprofen + Paracetamol	3	4.3
Diclofenac + Serratiopeptidase	1	1.4
Diclofenac + Thiocolchicoside	1	1.4

Table 5 : Prescription assessment according to WHO prescribing indicator

Prescribing indicators	Average/percentage (%)
The average number of drugs per prescription	4.22
Percentage of drugs prescribed by generic name	16.22%
Percentage of antibiotic prescribed	57.36%
Percentage of injection prescribed	65.79%
Percentage of drugs prescribed from NLEM- 2015	39.65 %
Percentage of drugs prescribed from the WHO model list of essential medicines –March 2017	24.81%

Table 6 : Price variation of different brands of NSAIDs

Drug	Dose& Dosage form	Number of brands	Minimum Cost (INR)	Maximum Cost (INR)	Percentage Price Variation
Diclofenac Sodium	50mg tab	6	0.61	4.16	581.96
	100mg SR tab	3	2.465	4.95	100.81
Diclofenac Potassium	50mg tab	2	1.280	4.55	255.46
Diclofeanc	25mg/ml inj	4	9	12.8	42.22
Etoricoxib	60mg tab	3	3.99	7.69	92.73
	60mg FC tab	5	4.946	6.745	36.37
	90mg tab	4	5.50	9.38	70.54
	90mg FC tab	5	6.7	7.95	18.66
	120mg tab	4	8.99	12.35	37.37
	120mg FC tab	5	8.7	12.35	41.95
Aceclofenac	100mg tab	13	0.99	3.4	243.43
	200mg SR tab	9	2.9	5.51	90.0
Aceclofenac+Paracetamol	100/325mg tab	4	3.85	5.0	29.87
	100/500mg tab	7	2.6	3.98	53.07
Diclofenac Na + Paracetamol	50/500mg tab	5	0.99	3.7	273.73
	50/325mg tab	4	1.4	3.8	171.43
Diclofenac+ Trypsin + Bromelain+ Rutoside	50/48/90/100mg tab	2	16.5	17.5	6.06
Ibuprofen + Paracetamol	400/500mg tab	2	1.35	1.4	3.7
Aceclofenac+ PCM +Chlorzoxazone	100/500/250 mg tab	2	6.4	7.4	15.62
	100/325/250 mg tab	3	2.9	5.75	98.27
Diclofenac Na + Paracetamol+ Chlorzoxazone	50/325/250 mg tab	2	3.73	8.0	114.47
Indomethacin	75mg SR cap	3	3.2	7.2	125.0
Diclofenac K + Metaxalone	50/400mg tab	2	9.25	9.7	4.8
Etoricoxib + Thiocolchicoside	60/4mg tab	2	17.5	18.1	3.42
Diclofenac sodium + Serratiopeptidase	50/10mg tab	3	5.8	6.3	8.62
	50/10mg FC tab	2	5.94	10.4	75.08
Diclofenac Potassium + Trypsin Chymotrypsin	50/50000AU tab	2	6.8	9.5	39.7

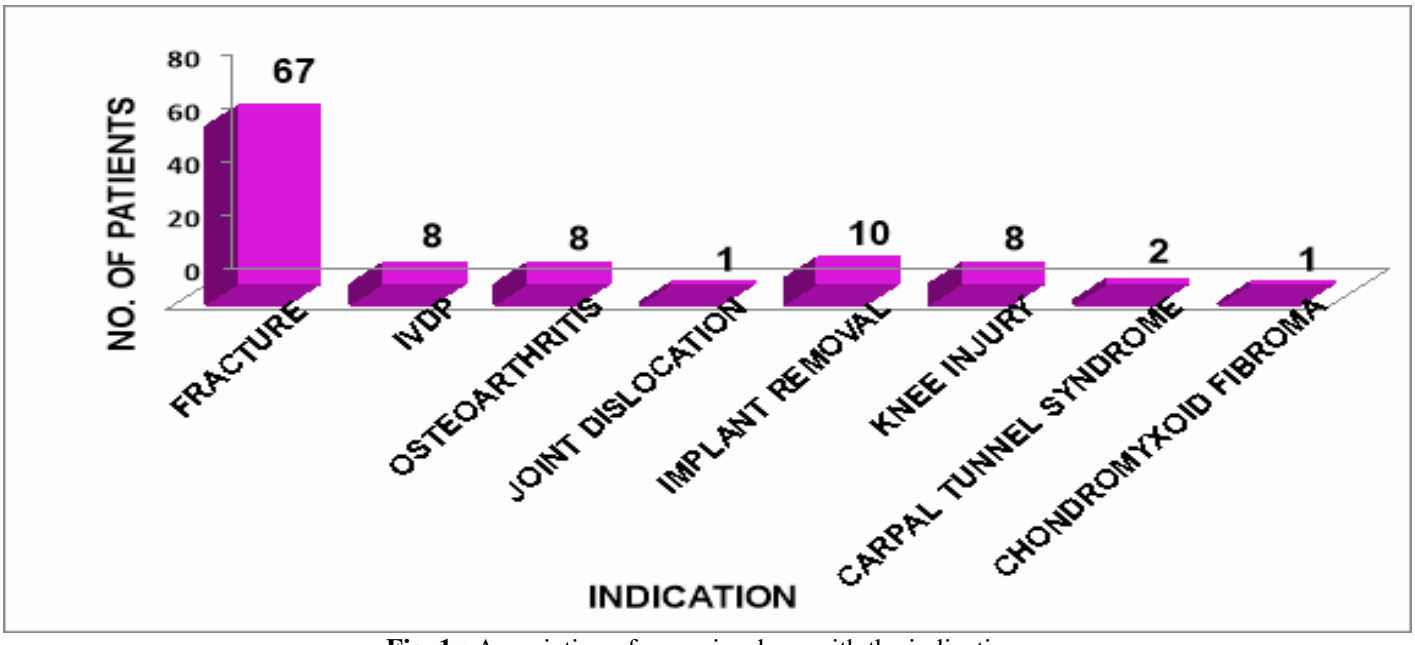

Fig. 1 : Association of surgeries done with the indications

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Conflict of Interest

Authors declare no conflict of interest

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