

A PHARMACOVIGILANCE STUDY OF ANALGESICS PRESCRIBED IN POST OPERATIVE PATIENTS ADMITTED IN ORTHOPAEDIC DEPARTMENT OF TERTIARY CARE HOSPITAL

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Abstract- The aim of the study to identify and analyze ADRs in post-operative orthopedic patients receiving analgesics and to determine the causality and safety profile of all the prescribed medications **Methods:** A prospective study was carried out in orthopedic department and total 196 patients fulfilling the inclusion criteria were enrolled in this study to observe the risk of adverse drug reactions (ADRs) due to Analgesics. All the ADRs were further analyzed in relation to age and sex, type of drug and its pattern, incidence, frequency, severity and causality **Results:** Out of 196 patients, ADR is seen in 56 patients receiving analgesics. Most common reported ADR was constipation (53.5%) followed by gastritis (26/7%) and dizziness (10.7%). The suspected ADRs were assessed for their causality, it was revealed that 15 were probable and 41 were possible as per WHO Scale. **Conclusions:** Analgesics are prescribed most commonly for post-operative control of pain and inflammation; therefore, active pharmacovigilance should be carried out so it will allow treating physician to identify the ADR associated with drugs which are commonly prescribed by the physicians which will in long term provide beneficial effect to patients.

Keywords--- NSAIDS, Opioids, Analgesics, Adverse drug reaction, WHO Scale, Causalty assessment

INTRODUCTION

Postoperative pain management is an important health concern, especially following orthopedic surgery. In clinical scenarios, patients undergoing orthopedic surgery would suffer a lot from pain, since pain can exist preoperatively, intraoperatively, and postoperatively. Pain can appear as a postoperative complication and may become chronic and last for a long time. ^[1]

Analgesics are drugs, which possess significant pain relieving properties by acting in the central nervous system or on peripheral pain receptors without significantly affecting consciousness. Mainly classified in two groups- 1) Narcotic/Opioid analgesics and (2) Non-narcotic/non-steroidal anti-inflammatory drugs (NSAIDs). ^[2]

Nonsteroidal anti-inflammatory drugs (NSAIDs) have been used to decrease pain and inflammation for post-operative pain in orthopedic patients and other conditions for decades. Opioid analgesics are used to treat moderate to severe pain with proven analgesic efficacy. Both the classes of drugs have their own adverse drug reaction, which if not considered can lead to burden on patient as well as treating physician ^[3]

The detection of Adverse Drug Reactions (ADRs) has become significant because Adverse drug reactions can result in loose of patient's confidence leading to negative emotions toward their physician's treatment and can engage in self-treatment options, which may consequently precipitate additional ADRs. ^[4]

Hence, the present study is planned to identify the ADRs due to Analgesics and to know how to monitor the drug's effect and to generate data on the safety profile of currently prescribed analgesics in post-operative orthopedic patient by doing monitoring of ADRs.

METHOD

This was a prospective observational study conducted over a period of 18 months (March 2021 – Aug 2022) on post-operative orthopedic patients admitted in orthopedic department of NSCB Medical College Jabalpur. All

the participants included in the study were explained clearly about the purpose and nature of the study in the language they understood and were included in the study only after obtaining a written Informed Consent.

Inclusion criteria • Post-operative patients who received analgesics and stayed at least one day to till discharge during study period. • Patients irrespective of age, gender, diagnosis and treatment.

Exclusion criteria

- Patients admitted in Orthopedic ward but transferred to other department.
- Patients who are absconded or discharged against medical advice.
- Patients with hepatic and/or renal impairment.
- Patients with cognitive impairment, critically ill or intubated.

A total of 196 patients were enrolled in the study and the data was collected in a specially designed data collection form. The individual data collected from the prescriptions was analyzed on the following parameters: Demographic profile, type of analgesics used and type of therapy - monotherapy or fixed drug combination (FDC) therapy and All the ADRs were further analyzed in relation to age and sex, type of drug and its pattern, incidence, frequency, severity and causality.

RESULT

In an 18 months' period from March 2021 – Aug 2022 a total of 196 post-operative patients admitted in the orthopedics department of NSCB Medical College, Jabalpur who met the inclusion criteria were included in the study and their prescriptions were analyzed. Out of 196 patients, 56 had developed ADR, out of which n=35 male had developed ADR while n=21 females had developed ADR. (FIG-1)

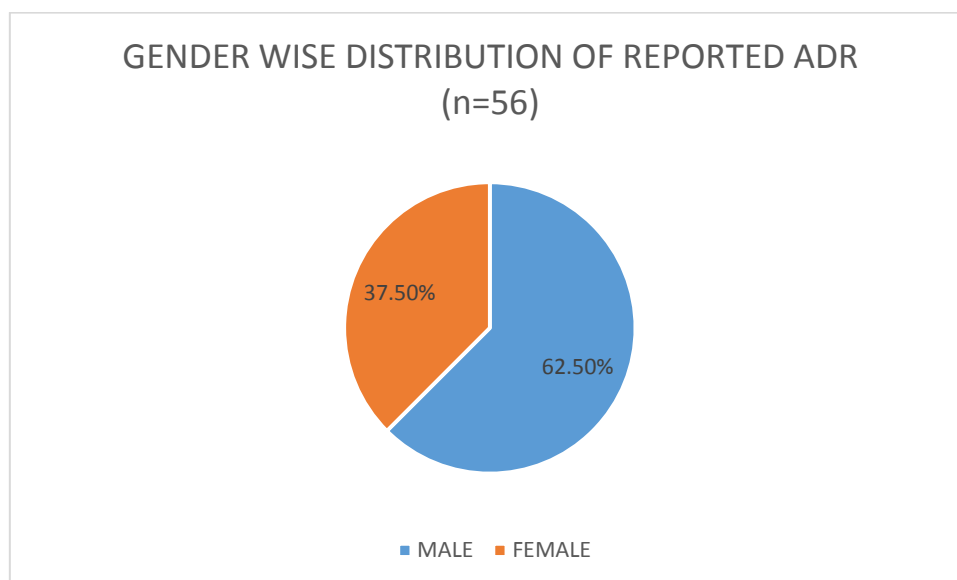


Figure 1 PERCENTAGE OF GENDER WISE DISTRIBUTION OF ADR

The number of patients who received NSAIDS was more than Opioids. Among NSAIDS, diclofenac was more commonly prescribed, hence the percentage of ADR was more with Diclofenac. Out of 56 ADRs, 25 (44.64%) were due to diclofenac, 10 (17%) were due to paracetamol and 5 (8.9%) were due to aceclofenac. Opioids induced ADR were also seen. Tramadol was second most commonly prescribed analgesic after Diclofenac. 16(28.5%) ADR were reported in patient receiving tramadol for post-operative pain management. [Table 1].

Table 1 DRUG UTILISATION AND ADVERSE DRUG REACTION

DRUG UTILISATION AND ADVERSE DRUG REACTION			
NAME OF ANALGESICS PRESCRIBED	NO OF PATIENTS	NO OF ADR (OUT OF 196 PATIENTS)	% OF ADR
DICLOFENAC	80	25	44.64%
ACECLOFENAC	21	5	8.93%
PARACETAMOL	30	10	17.86%
TRAMADOL	65	16	28.57%
TOTAL	196	56	100.00%

Most common reported ADR was constipation (53.5%) followed by gastritis (26.7%) and dizziness (10.7%). Distribution of ADR with different analgesics prescribed were given below. [Table 2 & Table 3]

Table 2 DISTRIBUTION OF SUSPECTED ADR AMONG PATIENTS

DISTRIBUTION OF SUSPECTED ADR AMONG PATIENTS		
SUSPECTED ADR	FREQUENCY	PERCENTAGE
Constipation	30	53.57%
Gastritis	15	26.79%
Headache	5	8.93%
Dizziness	6	10.71%
Total	56	100.00%

Table 3 ADR WITH DIFFERENT ANALGESICS DRUGS PRESCRIBED

ADR	DRUGS				
	DICLOFENAC	ACECLOFENAC	PARACETAMOL	TRAMADOL	TOTAL
Constipation	17	1	3	9	30
Gastritis	6	3	5	1	15
Nausea	2	1	1	1	5
Dizziness	0	0	1	5	6
TOTAL	25	5	10	16	56

The causality assessments of ADRs were also done according to WHO Scale which categorises ADRs as “certain”, “probable”, “possible”, “unlikely” and “unclassifiable”. It is seen that out of 56 ADRs reported with 15 were classified as probable and 41 ADRs as possible, whereas none could be categorized as certain or unlikely. [TABLE 2]

Table 4 CASUALTY ASSESSMENT OF ADR REPORTED

DRUGS	CERTAIN	PROBABLE	POSSIBLE	UNLIKELY	UNCLASSIFIED
DICLOFENAC	0	7	18	0	0
ACECLOFENAC	0	2	3	0	0
PARACETAMOL	0	0	10	0	0
TRAMADOL	0	6	10	0	0
TOTAL	0	15	41	0	0

DISCUSSION-

The study highlighted that the most commonly prescribed group of drugs was analgesics as most of the patients in orthopedic ward experience pain and inflammation post operatively. NSAIDs mainly diclofenac is preferred choice of NSAIDs in post-operative Orthopaedic patient. Among opioid analgesics, tramadol is the most commonly prescribed drug either alone or in combination with NSAIDs. The result was similar with the earlier study by Nagla and Wadagbalkar. [5]

In our study diclofenac was the most commonly prescribed NSAIDs followed by paracetamol, aceclofenac. Out of 80 patients who received diclofenac 25 (44.6%) developed ADRs which was in accordance with other 2 studies at Gujarat and Chennai. [6,7]

Limitation of the study was, it was single centered and the number of patients screened was less. Further studies may include larger study groups involving various departments.

CONCLUSION

In our study, Gastro-intestinal, metabolic disorders were most common ADRs reported. Monitoring of ADRs in post-operative patients taking analgesics is very important, Active pharmacovigilance should be carried out so it will allow treating physician to identify the ADR associated with drugs which are commonly prescribed by the physicians which will in long term provide beneficial effect to patient and also improves recognition of common ADRs by the medical students.

Acknowledgments

The authors appreciate the cooperation of all the co-authors for their constant support throughout the study period and patients who participated in the present study

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