Section: Orthopaedics

Original Research Article

A PROSPECTIVE OBSERVATIONAL DRUG UTILIZATIONAL STUDY OF ANALGESIC USE AMONG POSTOPERATIVE ORTHOPAEDIC PATIENTS IN TERTIARY CARE INSTITUTE

J Ajit Pratap Singh[1], Ashish Sirsikar[2] , Kapil Soni[3]

[1]Professor & Head, Department of Pharmacology, Netaji Subhash Chandra Bose Medical College, Jabalpur (M. P.), India.
[2]Associate Professor, Department of Orthopaedics, Netaji Subhash Chandra Bose Medical College, Jabalpur (M. P.), India.
[3]Post Graduate Student, Department of Pharmacology, Netaji Subhash Chandra Bose Medical College, Jabalpur (M. P.), India.

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Corresponding Author:
Dr. Ashish Sirsikar,
Email: drashishsirsikar@gmail.com

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Abstract

Background: Introduction: According to WHO, drug utilization study is about marketing, distribution, prescription and use of drugs in a society, with special emphasis on medical, social and economic consequences. Effective postoperative pain management is important to improve the outcome of patient care after any surgical intervention. Main aim of this study was to evaluate the prescription pattern of analgesics in post-operative patients at orthopaedic department. **Material and Methods:** A hospital based prospective observational study of 196 patients was carried out over a period of 18 months (March 2021 – Aug 2022) on postoperative patients of Orthopaedics Department. The clinical data included diagnosis, indications for analgesics prescribing, names of analgesics prescribed, the concomitant drugs prescribed, various co-morbidities, number of analgesics per prescription and drug interactions were analyzed. **Observations:** On Day 0, 1 and 2, maximum participants were given Inj. Diclofenac 75 mg. However, on day 3, maximum took Tab. Ibupara 400mg + 325 mg. Descriptive statistics shows that the mean of NRR score 0,1,2, and 3 among study participants are 8.34±.474 days, 6.39± 0.549 days, 5.33± 0.653 days and 3.44± 0.658 days respectively. **Results:** The association between day 0 and 1 with NPRS is highly significant. Similarly, with days 0 and 2, 0 and 3, 1 and 2, 1 and 3 and 2 and 3 are all significant (p-0.001). **Conclusion:** Drugs should be ideally prescribed by their generic names rather than brand/ trade names. In this era, where increased number of irrational drug combinations is being marketed aggressively, educating health-care providers regarding the national essential list of drugs and adhering to rational prescribing is the need of the hour. More studies of these types are needed in Indian rural population.

INTRODUCTION

According to WHO, drug utilization study is about marketing, distribution, prescription and use of drugs in a society, with special emphasis on medical, social and economic consequences.[1,2] Rational drug use is important for optimal benefit of drug therapy in patient care.

Postoperative pain is a form of acute pain due to the surgical trauma with inflammatory reaction.[6] Effective pain management is important to improve the outcome of patient care after any surgical intervention.[7] Ineffective management of postoperative pain causes stress in patient, decrease in mobility; it may cause deep vein thrombosis, atelectasis and changes in metabolic system. The selected analgesic should be more safe for that particular patient and adverse effects are minimized by selecting appropriate dose, route, technique of administration, etc.[11,12]

Periodic good postoperative analgesic management probably carries benefits other than increased patient comfort. Early mobilization can be achieved and the patient can be discharged from hospital sooner. In developing countries like India, where the financial resources are scarce and affordability of the patients is less, implementation of Rational use of medicines become more important and therefore, the assessment of drug utilization is vital for clinical, economic, and educational purposes.[12]

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Justification for Study

Prescription pattern analysis is part of drug utilization study; it improves the quality of prescription, reduces the adverse effects of drugs and enhances the rational use of drugs.[2] These types of studies are even more useful in developing countries where population burden, low socioeconomic status, lack of knowledge, etc are associated factors. Hence, this study was conducted to evaluate the prescription pattern of analgesics in post-operative patients at orthopedic department.

Aims & Objectives

Primary Objective

- To evaluate drug utilization pattern of analgesics in post-operative patients.

Secondary Objective

- To study the prescription pattern for rationality.
- To study the adverse drug reactions due to analgesic in post-operative patients.

MATERIALS AND METHODS

Study Period

1st March 2021 to 30th August 2022

Study area and target population: The present study was carried out in Department of Pharmacology in collaboration with Department of Orthopaedics of Netaji Subhash Chandra Bose Medical College & Hospital, Jabalpur (M.P.)

Sample Size 196

As it was an observational study with none of the ethical constrains, all feasible patients were included in the study. The minimum adequate required sample size was estimated to be 196 using following formula for prevalence of irrational analgesic prescriptions in postoperative patients –

$$n = \frac{z2 \times p(1-p)}{\varepsilon 2}$$

where,

n = Sample size; p = Prevalence of measure = 84.70% (Irrational analgesic prescriptions);

ε = Absolute precision, and Z = normal deviate for two-tailed alternative hypothesis at a level of significance; for example, for 5% level of significance, Zα/2 is 1.96. The confidence level is estimated at 95% with a z value of 1.96 the confidence interval or margin of error is estimated at ± 0.05. The minimum sample size required for the study was calculated to be 196.

Study Design Prospective Observational study.

Study Group The study will be conducted on the post-operative orthopaedic patients from Ward of Department of Orthopaedics, N.S.C.B.M.C.H., Jabalpur (M.P.)

Inclusion Criteria

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

Exclusion Criteria

- Patients admitted in Orthopaedic 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.

Data Collection Method

After a preoperative informed consent, all the data was recorded by using structured schedule (case report form) and entered in Microsoft Excel Sheet.

Tools Used

- Detailed History of symptoms and onset of problem.
- Clinical examination.
- Haematological investigations done at N.S.C.B Medical College, Jabalpur.
- WHO Guidelines for rational prescription.
- The WHO endorsed the Assistive Anatomic Therapeutic Chemical (ATC) and Defined Daily Dose (DDD) methodology.
- Numeric Pain Rating Scale (NPRS).
- PvPI ADR reporting form.

Ethical Issues

- This study was conducted after getting preoperative informed written consent from the patients in their local language.

Assessment of Patients

- This was a hospital based prospective observational study carried out over a period of 18 months (March 2021 – Aug 2022) on postoperative patients of Orthopaedics Department. The patients who were receiving analgesics in post-operative period in Orthopaedic Department during study period irrespective of age, sex, diagnosis and treatment were included.
- A total of 196 patients were enrolled in the study and the data was collected in a specially designed data collection form. The demographic data comprising age, sex was collected from the patient. The clinical data included diagnosis, indications for analgesics prescribing, names of analgesics prescribed, the concomitant drugs prescribed, various co-morbidities, number of analgesics per prescription and drug interactions were analyzed. Photographs of prescription were taken and copy was attached to patient case form for interpretation and analysis. WHO model list of Essential Medicines 2019 and WHO indicators of drug utilization was used to assess the rationality of analgesic use. The WHO endorsed the Assistive Anatomic Therapeutic Chemical (ATC), Defined Daily Dose (DDD) methodology used to calculate DDD.

DDD (Defined Daily Dose)

- The basic definition of the Unit is: The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults.

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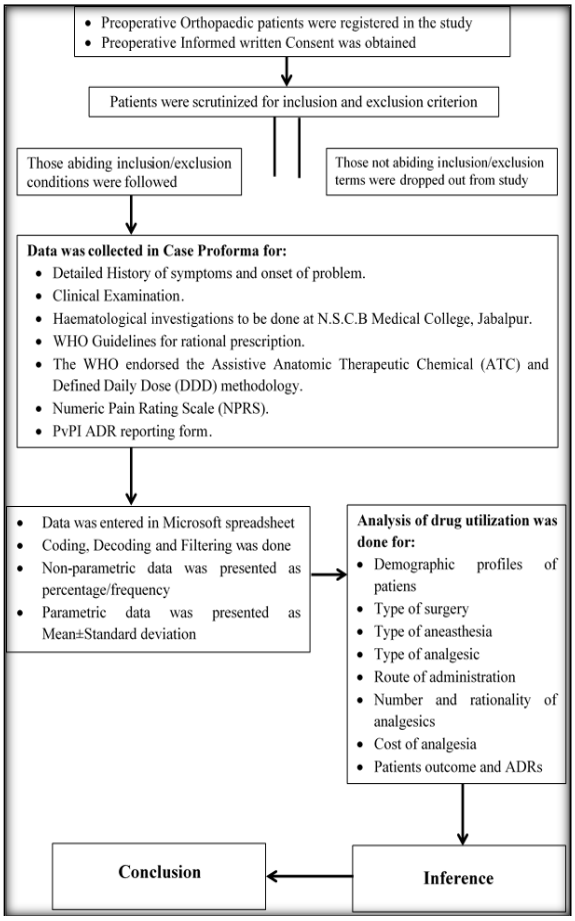
- The DDD is a unit of measurement and does not necessarily reflect the recommended or Prescribed Daily Dose. Therapeutic doses for individual patients and patient groups will often differ from the DDD as they will be based on individual characteristics (such as age, weight, ethnic differences, type and severity of disease) and pharmacokinetic considerations.

Sampling Method

- Considering the best availability of the patients by reviewing the previous records of the health facility, to achieve the maximum sample size, we screened all patients and selected those who fulfil the inclusion and exclusion criteria and were ready to have the written preoperative informed consent.
- Preoperative informed and written consent was obtained from each individual or legally eligible attender and participation in the project was kept totally on voluntary basis.
- Detailed information on the objectives of the study and research therapeutic protocol was provided to all subjects.

FLOW CHART



RESULTS

In our present study, majority of the study participants (144- 73.5%) were male, and rest (52- 26.5%) were females. Majority of the study participants (89- 45.4.5%) were 20-40 years old, and minimum 2(1.0%) were 80 years and above. Majority of the study participants (101- 51.53%) were workers by occupation. Most of them (141- 71.9%) were married. The most common complain among study participants (189- 96.4%) was pain and swelling. Most of them (143- 73%) had history of road traffic accidents, while 53 (27%) had history of fall. Majority of them (162- 82.6%) had fracture as final diagnosis.

On Day 0, maximum participants (82- 41.8%) were given Inj. Diclofenac 75 mg. Similarly, on day 1, maximum 108 participants were given Inj. Diclofenac, on day 2 also, maximum (99- 50.5%) took inj. Diclofenac 75 mg. However, on day 3, maximum (63- 32.1%) took Tab. Ibupara 400mg + 325 mg. In our present study, the adverse drug reaction was found only in 14 cases (7%), out of which, constipation, gastritis and nausea developed among 4 cases each, while two patients had headache. Out of these 14 ADR cases, maximum 6 (3.1%) patients received injection Tramadol. In Causality assessment among 14 ADR cases, 10 were probable and 4 were possible.

Table 1: Descriptive statistics (Mean and SD) for NPRS Score

NPRS Score (in days)	Mean	SD
0	8.34	.474
1	6.39	.549
2	5.33	.653
3	3.44	.658

In our present study, Descriptive statistics shows that the mean of NRR score 0,1,2, and 3 among study participants are 8.34±.474 days, 6.39± 0.549 days, 5.33± 0.653 days and 3.44± 0.658 days respectively. On day 0, maximum participants 114 (58.2%) were given combination therapy, however on day 1, maximum 108 participants were given monotherapy, on day 2 also maximum 120 (61.2%) also took combination therapy. However, on day 3 of admission maximum 154 (78.6%) took monotherapy.

On day 0, maximum participants 132 (67.3%) were given NSAIDS, however on day 1, maximum 156 participants were given NSAIDS, on day 2 also maximum 158 (80.6%) also took NSAIDS. However, on day 3 of admission maximum 113(57.7%) also took NSAIDS. In our present study, the association between day 0 and 1 with NPRS is highly significant. Similarly with days 0 and 2, 0 and 3, 1 and 2, 1 and 3 and 2 and 3 are all significant (p-0.001).

DISCUSSION

Pain consists of both sensory and affective (emotional) components. Opioid analgesics are unique in that they can reduce both the aspects of the pain experience, especially the affective component. In contrast, non-opioid steroidal and

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non-steroidal analgesic drugs have no significant effect on the emotional aspects of pain and will be more effective in relieving inflammation associated sensory component by inhibiting the synthesis of proinflammatory sensitizers like prostaglandin, NFkB, cytokines etc. Because age-related changes in pain processing occur in older patients, including suprathreshold pain responses may make it difficult to modulate respond to nociceptive input. So selection of analgesic should be done carefully.[10,11]

Fractures are among the most common orthopaedic problems, and about 6.8 million people seek medical care attention for fracture in India and most common indication for prescribing analgesics was fractures. Prescribing drugs by generic name, promote the rational use of drugs with regard to safety, efficacy, and cost by permitting the identification of the products by its scientific names. Increasing generic prescribing would rationalize the use and reduce the cost of drugs. Globally, NSAIDs are most commonly prescribed drugs for the management of pain and inflammation and the same has been reflected in this study.[12-15] The present study shows that Diclofenac was the most frequently used non-opioid analgesic by intravenous route. Diclofenac has been chosen both as mono and in combination with other drugs. As it is a nonselective COX inhibitor, it will be effective in relieving inflammation induced moderate and severe pain.[16-19]The advantage of diclofenac usage for post-operative pain is that it can be administered parenteral in initial post-operative period which can be converted to enteral route later on 2nd and 3rd post-operative day. But being a selective COX-3 inhibitor, Paracetamol is said to have more antipyretic effect than analgesic effect. Nonopioid drugs have been shown to produce lesser side effects than opioid drugs. Usage of Non-opioids can decrease the requirement of opioid analgesic in the early post-operative period also. Majority of the studies suggest that, non-opioid analgesics are the preferred drugs for the treatment of postoperative pain relief.

Despite the wide clinical use of NSAIDs, their gastrointestinal toxicity is the major limitation in clinical use. Hence, they are coprescribed with gastroprotective agents. We found 22.36% of analgesics being co-prescribed with gastroprotectives. The average number of drugs per prescription is an important parameter while doing a prescription audit. Multiple drug prescribing results polypharmacy, this may cause to irrational prescribing and induce adverse effect.

Analyzing the results of these indicators, information was obtained about the "quality of prescribing the drug" to quantity in different circumstances of use (time, duration, age of the patient, route of administration, etc.). The calculation of DDD/100 bed-days for drug utilization is used as a tool to measurement the pattern of consumption of analgesics. In this study, the total drug utilization of analgesics at inpatients department during the study in terms of DDD/100 bed-days was 127.62. The WHO has recommended the ATC classification/DDD system as a tool for presenting drug utilization research to improve the quality of drug use. This study revealed that most of the analgesics were prescribed for appropriate indication. The duration of prescribing of analgesics was found to be satisfactory in this study.

CONCLUSION

Based on the observations of the present study, it is concluded that NSAIDs in that diclofenac was the most commonly prescribed analgesic for postoperative pain relief, both in monotherapy and combination therapy in the post operative orthopaedic patients of Netaji Subhash Chandra Bose Medical College and Hospital, Jabalpur, Madhya Pradesh.

Post-operative pain can be better managed by non-opioid analgesics like diclofenac. A combination of NSAIDs with opioids like tramadol should be reserved for patients not responding to diclofenac alone. NSAIDs like diclofenac are better suited for short course analgesic therapy like post-operative pain management (<10 days), due to their cost-effectiveness and less adverse effects.

Drugs should be ideally prescribed by their generic names rather than brand/ trade names. In this era, where increased number of irrational drug combinations is being marketed aggressively, educating health-care providers regarding the national essential list of drugs and adhering to rational prescribing is the need of the hour. Drug utilization studies promote use of rational prescription pattern and this improves the safety, efficacy of drugs and decreases the cost of treatment. More studies of these types are needed in Indian rural population.

Recommendations

We recommend that

- Studies should be done in all departments of the hospital to generate data regarding pattern of analgesic utilization in our hospital. This should be done for both inpatients and outpatients.
- Guidelines for appropriate use of analgesics in our hospital need to be made.
- Training in rational use of analgesics must be a part of all undergraduate and postgraduate medical curriculums, involved in pain management.

Limitations of The Study

- There are some limitations of present study, first and foremost it is observational study, no intervention has been done. It is single centric study; observation may not be same for other region and in the same region at different time.

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