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SAFETY REPORTING STUDY OF NONSTEROIDAL ANTI-INFLAMMATORY DRUGS

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Abstract

Background: The nonsteroidal anti-inflammatory drugs (NSAIDs) are among the most frequently used drugs to treat pain and inflammation. Although NSAIDs are having enormous clinical use, but are not devoid of adverse drug reactions (ADRs) as peptic ulcer, gastritis, renal, neurological reactions etc.

Methods: Total 500 Orthopaedic out-patients of SIMS, Hapur were enrolled in the study to observe the risk of ADRs due to NSAIDs. All the ADRs were further analysed in relation to age, sex, types of drug and its pattern etc. The causality was analysed by using Naranjo's Algorithm and severity was analysed by using the Hartwing and Siegel scale.

Results: In this study the incidence rate of the ADRs was around 5.6%. Among the 28 patients who had developed ADRs, a total 10 kinds of ADRs were observed. The reactions that affected the study subjects were gastritis, nausea, vomiting, abdominal Pain, diarrhoea, urticaria, pruritus, headache, rash, ankle oedema and dizziness. Majority (23 cases) of ADRs were mild in their severity and that 5 cases ADRs were moderate in nature. All the ADRs were treated symptomatically by using standard treatment protocols.

Conclusion: In this study, incidence of adverse reactions to nonsteroidal anti-inflammatory drugs was 5.60% and the most common implicated drug for the ADRs were Diclofenac sodium. Most of the adverse effects were mild and tolerable.

Keywords: Adverse drug reactions, Nonsteroidal anti-inflammatory drugs, Pharmacovigilance

Introduction

Pain is a qualitative, subjective feeling and management of pain is also very important in patients. Accurate diagnosis of disease with appropriate treatment of pain is pivotal for the well-being of the patients suffering from acute and chronic pain. Analgesics have been identified as one of the most commonly prescribed drugs for pain management and provide highest quality of life possible for patients with their disease conditions. It is an inter-disciplinary approach for easing the suffering and improving health of those living with pain. NSAIDs are among most widely used drugs with analgesic, antipyretic and antiinflammatory effect. NSAIDs constitute the largest single group of drugs used world-wide, constituting more than 20% of all drug prescriptions.[1] Other than their different therapeutic uses NSAIDs are also one of the common causes of adverse drug reactions reported to drug regulatory organizations as well as in many clinical and epidemiological studies. The use of NSAIDs is most frequent predisposing factor for peptic ulcer and approximately 10-20% patients who receive prolonged NSAID therapy develop asymptomatic peptic ulceration and ulcer related complications (bleeding, perforation, malignancy) that develops in 1-2% persons per year.[2]

The identification, assessment and prevention of ADR is an important mandatory process of hospitals. Pharmacovigilance, though an integral part of drug therapy but still it is not widely executed in Indian hospitals.

Methods

The prospective, observational study was conducted at department of Pharmacology, SMS Medical College, Jaipur, Rajasthan. All the newly registered patients of either sex, of the age groups between 18 to 70 years, who were on NSAID therapy for various painful, inflammatory condition were included for the study.

Patients with history of liver or kidney damage, cardiovascular disease, acid peptic disease, pregnant and lactating females were all excluded from the study.

A total 500 patients were enrolled after getting their informed and written consent as per the inclusion and exclusion criteria. Demographic details, diagnosis, medical history, details of their examination and concomitant medications were recorded with proper proforma.

Detailed history of ADR (drug name, dose, frequency, date of onset, pattern etc) was recorded in separate proforma. A structured questionnaire was used to record the adverse effect. The causality was assessed by using Naranjo's Algorithm, which is one of the most widely used methods for evaluating adverse reactions. It consists of 10 questions and each question was given a score. The total score was recorded for each patient and graded as definite, probable, possible and doubtful. The severity of the ADRs were grouped as mild, moderate or severe (assessed by using the Hartwing and Siegel scale) [3,4]

Results

Among the sample size of 500 patients who were treated with NSAIDs 28 patients had developed ADRs (n=28).

Table 1: Socio-demographic variable

Variable	ADR absent (n=472)	Present (n=472)	p-value
Age in yrs	46.32±9.65	44.29±8.56	0361
Male : Female	312 : 160	19 : 9	0.214

Out of 500 patients 331 patients were male and 169 were female.

Table 2: Drug utilization and ADRs

Drug	No of patients	Number of ADR
Diclofenac sodium	220	16
Paracetamol	106	4
Nimesulide	67	5
Ibuprofen	62	2
Etoricoxib	45	1

In this study the incidence rate of the ADRs was around 5.6%. Among the 28 patients who had developed ADRs, a total 10 kinds of ADRs were observed. The reactions that affected the study subjects were gastritis, nausea, vomiting, abdominal Pain, diarrhoea, urticaria, pruritus, headache, rash, ankle oedema and dizziness. Majority (23 cases) of ADRs were mild in their severity and that 5 cases ADRs were moderate in nature. All the ADRs were treated symptomatically by using standard treatment protocols.

Discussion

This potential study findings underline the incidence and pattern of ADR of analgesics like NSAIDs in Orthopaedic setting in the Indian scenario. The prevalence rate of ADRs to NSAIDs in our study was 5.60%.

A study conducted in Mumbai revealed the incidence rate of various kinds of ADRs of NSAIDs ranging between 28% to 33%, higher than our findings.[5]

In another recent study on adverse drug reactions of NSAIDs in orthopaedic patients of Delhi reported that the prevalence rate of ADR was 26%.[6] But decreased incidence rate of 5.5% was found as seen in a study by Venkatachalam that was relatively closer with our study findings.[7]

Rational usage of NSAIDs, their proper selection and selection of proper treatment guideline protocols are important for decreased number of ADRs in the present study. During the study, majority of the ADRs were reported by active surveillance and it was observed that spontaneous reporting rate was also increased by clinical physicians.

Conclusion

Strict adherence to the pharmacovigilance guidelines reduced ADRs and economical burden on patients. It had also attributed to the better prescription practice which was followed by this hospital setup.

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