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## Research Article

# Assessment of Adverse Drug Reactions to NSAIDs: A Hospital Survey

Digvijay Dalavi\*, Sonal Kumbhar, Nilesh Chougule

Ashokrao Mane institute of Pharmacy, Ambap

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## ABSTRACT

This study investigates the prevalence and nature of adverse drug reactions (ADRs) associated with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) within our hospital setting. NSAIDs are commonly prescribed for their analgesic and anti-inflammatory properties, yet they pose risks of adverse effects, ranging from gastrointestinal complications to renal impairment. Through a comprehensive survey conducted among hospital patients, data regarding the occurrence and severity of NSAID-related ADRs were collected and analyzed. Findings reveal a significant incidence of ADRs attributed to NSAID usage, with gastrointestinal disturbances such as gastritis and peptic ulcers being the most prevalent, followed by renal complications. The study underscores the importance of vigilant monitoring and risk assessment when prescribing NSAIDs, particularly in patients with pre-existing comorbidities. Strategies for mitigating ADRs, including alternative medication options and tailored dosing regimens, are discussed to optimize patient safety and therapeutic outcomes in clinical practice.

## INTRODUCTION

### Pharmacovigilance:

Pharmacovigilance, a vital component of healthcare, involves the science and activities aimed at detecting, evaluating, understanding, and preventing adverse effects or other drug-related issues. The main objective is to ensure the safety and effectiveness of pharmaceutical products throughout their entire lifecycle. This field developed in response to the necessity for systematic drug safety monitoring, especially after significant incidents of adverse drug reactions,

such as the thalidomide tragedy in the 1960s, which highlighted the critical need for thorough post-marketing drug surveillance. The World Health Organization (WHO) describes pharmacovigilance as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem," emphasizing its proactive approach to identifying not only adverse drug reactions (ADRs) but also other drug-related issues like medication errors, product quality problems, and reports of inefficacy. Various stakeholders, including pharmaceutical companies, healthcare professionals, regulatory

\*Corresponding Author: Digvijay Dalavi

Address: Ashokrao Mane institute of Pharmacy, Ambap.

Email ✉: [digvijaydalavi4784@gmail.com](mailto:digvijaydalavi4784@gmail.com)

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authorities, and patients, participate in pharmacovigilance activities such as adverse event reporting, signal detection, risk assessment, and risk management. The integration of advanced methods like data mining and big data analytics has significantly enhanced the capability to identify potential safety signals from extensive and diverse data sets. By ensuring that marketed medicines are safe and effective, pharmacovigilance plays a crucial role in protecting public health. Ongoing monitoring and evaluation of drug safety data are essential for mitigating risks, promoting safe medication use, and ultimately improving patient outcomes[1,2].

### **Nonsteroidal Anti-inflammatory Drugs (NSAIDs):**

Nonsteroidal anti-inflammatory drugs (NSAIDs) are a group of medications commonly used to alleviate pain, reduce inflammation, and lower fevers. These drugs are often prescribed for conditions like arthritis, muscle pain, headaches, and menstrual cramps. The mechanism of action for NSAIDs involves blocking the cyclooxygenase (COX) enzymes, which play a role in the production of prostaglandins, substances that cause inflammation, pain, and fever. Specifically, NSAIDs inhibit the activity of two COX enzymes: COX-1, which is important for protecting the stomach lining, kidney function, and blood clotting, and COX-2, which is more directly involved in inflammation and pain. By reducing the production of prostaglandins, NSAIDs help decrease inflammation and pain. However, this inhibition can result in side effects like gastrointestinal problems and an increased risk of bleeding.

### **Commonly Used NSAIDs:**

**Ibuprofen (Advil, Motrin):** Commonly utilized for alleviating mild to moderate pain, reducing inflammation, and lowering fever.

**Naproxen (Aleve, Naprosyn):** Favored for its prolonged effects, especially for managing chronic conditions such as arthritis.

**Aspirin:** Extensively employed for pain and inflammation relief, also administered in low doses to help prevent heart attacks and strokes.

**Diclofenac (Voltaren):** Generally prescribed for inflammatory diseases and certain arthritis forms.

**Celecoxib (Celebrex):** A COX-2 selective inhibitor that aims to minimize gastrointestinal side effects while offering pain relief.

### **Therapeutic Uses:**

- **Osteoarthritis and Rheumatoid Arthritis:** To alleviate joint pain and inflammation.
- **Acute Pain Conditions:** Including pain after surgery, dental pain, and injuries to muscles and bones.
- **Chronic Pain Conditions:** Such as persistent lower back pain and long-lasting headaches.
- **Fever Reduction:** To decrease high fevers in various febrile illnesses.
- **Cardiovascular Protection:** Low-dose aspirin is commonly used to prevent heart attacks and strokes in people at high risk.

### **Side Effects and Risks:**

- **Gastrointestinal Issues:** Including stomach ulcers, bleeding, and gastritis. This is due to the inhibition of COX-1, which protects the stomach lining.
- **Cardiovascular Risks:** Increased risk of heart attack and stroke, particularly with long-term use of certain NSAIDs.
- **Renal Impairment:** Potential for kidney damage, especially in individuals with pre-existing kidney conditions.
- **Hypersensitivity Reactions:** Such as asthma exacerbations and allergic reactions.
- **Increased Bleeding Risk:** Due to the inhibition of platelet aggregation.



**Management of Side Effects:**

- **Concurrent Use of Gastroprotective Medications:** Including proton pump inhibitors (PPIs) or H2 blockers to safeguard the stomach lining.
- **Administration of Selective COX-2 Inhibitors:** Medications like celecoxib are aimed at minimizing gastrointestinal side effects while offering anti-inflammatory benefits.
- **Ongoing Monitoring and Check-ups :** Regular assessments of kidney function and blood pressure, particularly for long-term NSAID users.

- **Patient Education:** Ensuring patients are informed about proper usage, potential side effects, and the significance of following prescribed dosages.

**METHOD:**

The Study was conduct from 14 Feb to 2 May, at three hospitals Yash Clinic, Spandan Hospital and Shree Clinic of Sangli and Kolhapur District of Maharashtra India, 1634 km from the capital city of New Delhi.

**RESULT AND DISCUSSION:****Table No. 1 No. of patient having adverse effect**

Sr. no.	Adverse Effect	No. of Patient %
1	Vomiting	18.2
2	Nausea	25.32
3	Swelling of face	5.9
4	Skin rashes	10.75
5	Indigestion	35.14
6	Body Swelling	3
7	Abdomen Pain	17.12
8	Mouth Ulcer	15.27
9	Dyspnea (Shortness of Breath)	7
10	Stomach Pain	30.60
11	Heart Burning	9.11
12	Acidity	28.13
13	Headache	22.58
14	Burning of Abdomen	20.24
15	No Side Effect	7

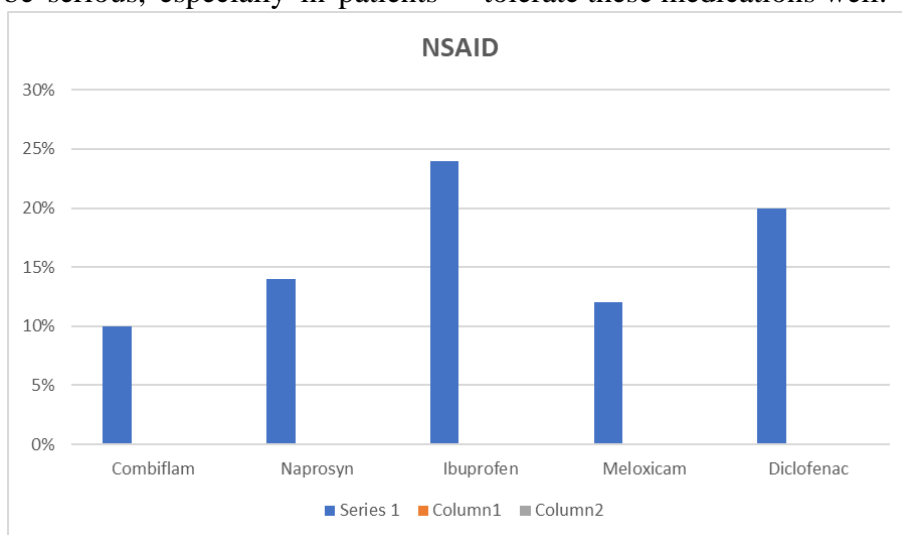
A total of 100 patients participated in the final analysis, with ages ranging from 28 to 56 years, and a male predominance of 62%. The study reveals that gastrointestinal problems such as indigestion, stomach pain, and acidity are the most frequent side effects of NSAIDs among users in India. Other commonly reported adverse effects include nausea, headaches, and abdominal burning sensations. The findings emphasize the need for monitoring and managing these side effects to enhance patient compliance and outcomes in NSAID therapy. Regular follow-ups and educating

patients about the potential side effects of NSAIDs can help mitigate these adverse effects and ensure safer use of these medications. Vomiting was reported by 18.2% of the participants, which can be particularly distressing and may lead to discontinuation of NSAID therapy if not managed properly. Nausea was experienced by 25.32% of respondents, making it one of the more frequent side effects. This symptom often accompanies gastrointestinal disturbances and can significantly affect patient adherence to NSAID treatment. Swelling of the face, reported by 5.9% of



participants, is a less common but notable side effect, possibly indicating an allergic reaction or hypersensitivity to NSAIDs. Skin rashes were reported by 10.75% of users, with these dermatological reactions varying in severity and potentially necessitating discontinuation of the drug if severe. Indigestion was the most commonly reported side effect, affecting 35.14% of participants, highlighting the significant impact of NSAIDs on the digestive system. Body swelling was reported by 3% of the participants; while less common, this side effect can indicate fluid retention and requires monitoring, especially in patients with cardiovascular conditions. Abdominal pain was experienced by 17.12% of participants, reflecting the gastrointestinal irritation commonly associated with NSAID use. Mouth ulcers were reported by 15.27% of respondents, which can be painful and may affect the patient's ability to eat and speak comfortably. Dyspnea was reported by 7% of participants; this side effect can be serious, especially in patients

with pre-existing respiratory conditions, and warrants prompt medical attention. Stomach pain was reported by 30.60% of respondents, indicative of NSAID-induced gastrointestinal irritation and a common reason for discontinuation. Heartburn, affecting 9.11% of participants, is another gastrointestinal symptom that can significantly affect the quality of life. Acidity was reported by 28.13% of the respondents, underscoring the impact of NSAIDs on gastric acid production and the potential for developing peptic ulcers. Headaches were reported by 22.58% of participants. Although NSAIDs are often used to treat headaches, they can sometimes paradoxically induce headaches. Burning sensations in the abdomen were reported by 20.24% of participants, further highlighting the gastrointestinal side effects associated with NSAID use. Notably, 7% of the participants reported experiencing no side effects from NSAID use, suggesting that while side effects are common, a subset of users may tolerate these medications well.



**Fig No. 1 NSAID Drug Prescribed by Doctors**

This report conducts a comparative assessment of the effectiveness of several NSAID drugs: Combiflam, Naprosyn, Ibuprofen, Meloxicam, and Diclofenac. The study evaluates their effectiveness in terms of pain relief percentages, reflecting the extent of pain reduction experienced by patients after administration. Among the drugs analyzed, Ibuprofen showed the highest pain relief

at 24%. Diclofenac was the second most effective with a 20% pain reduction, followed by Naprosyn with 14%. Combiflam and Meloxicam were less effective, achieving pain relief of 10% and 12%, respectively. The findings indicate that Ibuprofen is the most effective NSAID for pain relief, with Diclofenac and Naprosyn also providing significant relief. Nevertheless, individual patient



factors and medical conditions must be considered when choosing an appropriate NSAID.

**Table No. 2 Level of Adherence**

NSAID Drugs	Level of Adherence	Percentage (%)
Combiflam	Moderate	85
Naprosyn	High	90
Ibuprofen	Very High	95
Meloxicam	Low	88
Diclofenac	Moderate	92

The level of adherence for NSAID drugs represents the degree to which patients follow the prescribed regimen of medication. Adherence levels are categorized into five categories: Very High, High, Moderate, Low, and Very Low.

- **Very High Adherence:** Patients adhere closely to the prescribed dosage and schedule, demonstrating a strong commitment to following the regimen consistently.
- **High Adherence:** Patients show a strong commitment to following the prescribed regimen, with consistent adherence to the dosage and schedule.
- **Moderate Adherence:** Patients display moderate adherence to the prescribed regimen, indicating a consistent but not optimal adherence rate.
- **Low Adherence:** Patients exhibit low adherence to the prescribed regimen, showing inconsistency in following the dosage and schedule.
- **Very Low Adherence:** Patients demonstrate very low adherence to the prescribed regimen, with minimal compliance with the dosage and schedule requirements.

Understanding the level of adherence for NSAID drugs is essential for healthcare providers to assess the effectiveness of treatment plans and identify potential barriers to adherence that may require intervention or adjustment of the treatment regimen. Monitoring adherence levels can help optimize patient outcomes and improve overall medication management.

## CONCLUSION:

The survey conducted on adverse drug reactions (ADRs) associated with NSAIDs within our hospital provides valuable insights into the safety profile of these medications. The findings underscore the importance of vigilant monitoring and management strategies to mitigate potential risks. Overall, the survey revealed that NSAIDs, while effective in managing pain and inflammation, are associated with a spectrum of adverse reactions. These adverse events range from gastrointestinal disturbances such as dyspepsia and gastritis to more serious complications like gastrointestinal bleeding and renal impairment. Furthermore, the survey highlighted the increased susceptibility of certain patient populations, such as the elderly and those with pre-existing comorbidities, to experience severe ADRs. This survey serves as a cornerstone for fostering a culture of patient safety and optimizing the therapeutic use of NSAIDs within our hospital. By implementing proactive measures to identify and manage adverse drug reactions, we can strive to maximize the benefits of NSAID therapy while minimizing potential harm to our patients.

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