

## DRUG UTILIZATION PATTERN OF PATIENTS USING NSAIDS IN SOUTH DELHI HOSPITAL

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## ABSTRACT

Objective: To evaluate the drug utilization of the Non-Steroidal anti-inflammatory drugs in South Delhi Hospital.

Method: The study was a simple randomised prospective survey study. This prospective study was carried out for a period of six months in selected areas of South Delhi region.

Key findings: Randomly selected 300 subjects were selected. During the six month study period, total of 300 patients were enrolled as per the inclusion and exclusion criteria. Among the 300 study patients 157 (52.3%) were male and 143 (47.6%) were females. It was observed that maximum number 83 (27.6%) were in the age range of 31-40 years followed by 68 (22.6%) patients in the range of 41 – 50 years. During the study it was observed that Aryl acetic acid derivatives (Aceclofenac, Diclofenac) were the most frequently prescribed drugs category (52.5%) followed by Paracetamol (26.6%), Ibuprofen (10.5%), Nimesulide (6.26%), Lornoxicam (4%). Among the individual drugs aceclofenac was the most commonly prescribed drug (32%), followed by Paracetamol (26%), Ibuprofen (10.5%), and Nimesulide (6.26%) & combination therapy were preferred. 143 (47.6%) of total patients showed a good adherence with the prescribed treatment. Adherence was found to be slightly better in females (24.3%) than in male (23.3%).

Conclusions: NSAIDs users were more prevalent in middle age groups (40yrs) patients and in male. Aryl acetic acid (Diclofenac & Aceclofenac) was the most frequently prescribed drug followed by Paracetamol, Ibuprofen and Nimesulide, Lornoxicam. Combination therapy was the preferred mode of therapy, few of the patients showed poor compliance, Average number of drugs per prescription was found to be 1.65%.

**Keywords:** Prospective, Drug utilization study, Adherence, NSAIDs, Compliance.

## INTRODUCTION

Non-steroidal anti-inflammatory drugs (NSAIDs) are drugs with analgesic, antipyretic and anti-inflammatory effects.<sup>1</sup> NSAIDs are among the most widely used drug in the developed countries, especially in the treatment of disorders associated with pain and inflammation.<sup>2</sup>

Prostaglandins are mediators of pain, inflammation and fever; in addition they play a role in protecting gastric mucosa, renal function and platelet activity. Anti-inflammatory drugs act by interfering with the production of prostaglandins by inhibiting the enzyme cyclooxygenase (COX), this results in reduction of inflammation and pain-desired effect while at the same time reducing protection to gastric mucosa, renal and platelet function- undesired effects. COX-2 inhibitors are thought to act by selectivity blocking COX-2, thereby reducing pain and inflammation, but not blocking COX-1. Standard NSAIDs are known to block both COX-1 and COX-2, reducing inflammation but at the same time blocking the protective role of COX-1, thus producing adverse effects, particularly on the gastric mucosa.

NSAIDs are usually indicated for the treatment of acute or chronic conditions where pain and inflammation are present. Example; Pyrexia, Rheumatoid arthritis, Gout, Dysmenorrhoea, Metastatic bone pain, Migraine, Postoperative pain, Antiplatelet, etc. Research continues into their potential for prevention of colorectal cancer, and treatment of other conditions, such as cancer and cardiovascular disease.

NSAIDs are associated with certain adverse drug reactions such as; allergic reactions, skin reactions, gastrointestinal effects, renal complications, alteration of hepatic enzyme levels and rarely hepatopathies.<sup>3</sup> These effects are dose-dependent, and in many cases severe enough to pose the risk of ulcer perforation, upper gastrointestinal bleeding, and death, limiting the use of NSAID therapy. Many of these events are avoidable; a review of physician visits and prescriptions estimated that unnecessary prescriptions for NSAIDs were written in 42% of visits.<sup>4</sup>

Non-steroidal anti-inflammatory drugs have shown an 80% increase in the risk of myocardial infarction with both newer Cox-2

antagonists and high dose of traditional anti-inflammatory compared with placebo.<sup>5</sup> Incidence of CV risk has posed some questions on the CV safety profile of the whole class.<sup>6</sup>

The risk of serious gastrointestinal complications in NSAID users is four times as high as that in non-users.<sup>7</sup> Upper GIT bleeding is the most common serious complication of NSAIDs use.

Renal ADRs is due to changes in renal haemodynamics (blood flow), mediated by prostaglandins, which are affected by NSAIDs. By blocking these prostaglandin-mediated effects, NSAIDs ultimately may cause renal impairment. It may ultimately cause salt and fluid retention, hypertension, interstitial nephritis, nephrotic syndrome, renal failure.

Although not direct teratogens, NSAIDs are not recommended during pregnancy, particularly during the third trimester. They may cause premature closure of the fetal ductus arteriosus and renal ADRs in the fetus, also they are linked with premature birth.<sup>8</sup>

## MATERIALS AND METHODS

In this Study 300 patients in OPD & IPD using NSAIDs were included. The study was a simple randomised prospective survey study. This prospective study was carried out for a period of six months in selected areas of South Delhi region. The study was approved by Jamia Hamdard Institutional Review Board (IRB). The subject were selected on the basis of inclusion & exclusion criteria. The inclusion criteria are: Patients of either sex were included after appropriate consent, Patients treated with at least one NSAIDs, Pregnant and lactating patients were also included, All the patients already receiving non-steroidal anti-inflammatory drugs before starting of the study & the exclusion criteria are: Patients who are not treated with NSAIDs, All the mentally retarded and unconscious patients, Drug addicts, Patients unable to comply, Patients refusing the consent.

## Sources of Data

- Physician prescribing records.
- Patient's medication profile.
- Study design Performa. (Questionnaire)

- Drug Utilization monitoring form (Appendix I).

**RESULTS AND DISCUSSION**

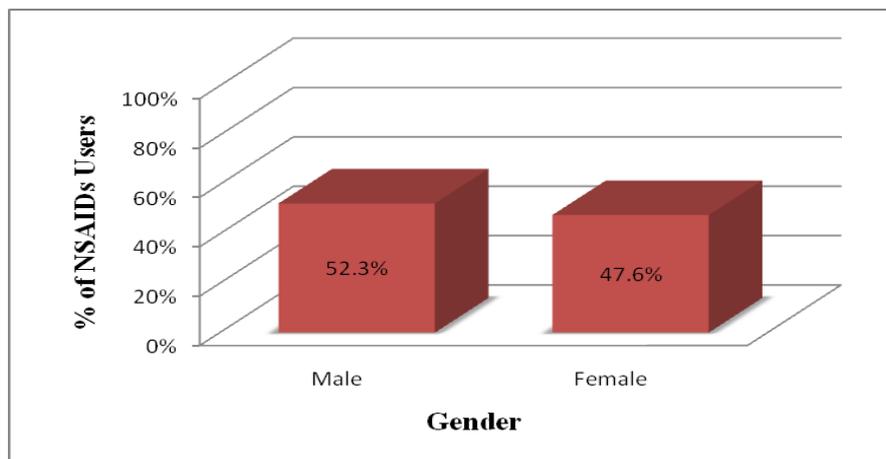
Randomly selected 300 subjects were selected.

**Distribution characteristics among study population**

Over a period of 6 months, 300 NSAIDs users were observed for the study. Among the 300 study patients 157 (52.3%) were male and 143 (47.6%) were females (Table 1, Fig 1)

**Table 1: Gender Distribution of NSAIDS Users**

Gender	No. of Patients	% of Patient
Male	157	52.3%
Female	143	47.6%
Total	300	100%



**Fig. 1: Gender Distribution of % of NSAIDs users**

**Age Distribution of NSAIDS Users**

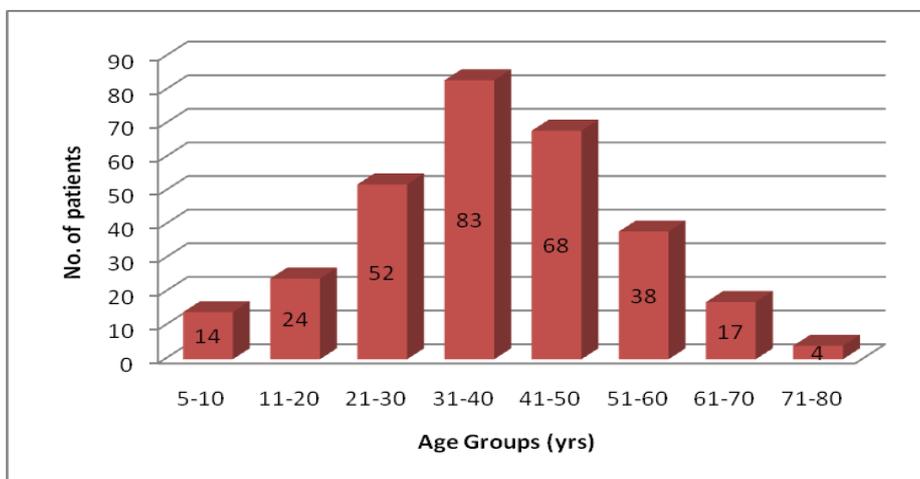
Among the 300 NSAIDs users, it was observed that maximum number 83 (27.6%) were in the age range of 31-40 years followed by 68 (22.6%) patients in the range of 41 – 50 years. (Table 2, Fig 2)

**Distribution of NSAIDS Users in OPD & IPD**

The distribution of patients in OPD & IPD was 86.6% & 13.3% respectively. (Table 3, Fig 3)

**Table 2: Age distribution of NSAIDS users**

Age (yrs)	Male	Male %	Female %	Female %	Total no. of Patients	Total % of patients
05-10	09	3.0	5	1.6	14	4.6
11-20	16	5.3	8	2.6	24	8
21-30	23	7.6	29	9.6	52	26
31-40	53	17.3	30	10	83	27.6
41-50	31	10.3	37	12.6	68	22.6
51-60	19	6.3	19	6.3	38	12.6
61-70	04	1.3	13	4.3	17	5.6
71-80	02	0.6	02	0.6	04	1.3
<b>Total</b>	<b>157</b>	<b>52.33</b>	<b>143</b>	<b>47.6</b>	<b>300</b>	<b>100.0</b>



**Fig. 2: Age distribution of NSAIDs users**

Table 3: Distribution of NSAIDs users in OPD & IPD

Department	No. of patients	% of patients
OPD	260	86.6%
IPD	40	13.3%
Total	300	100

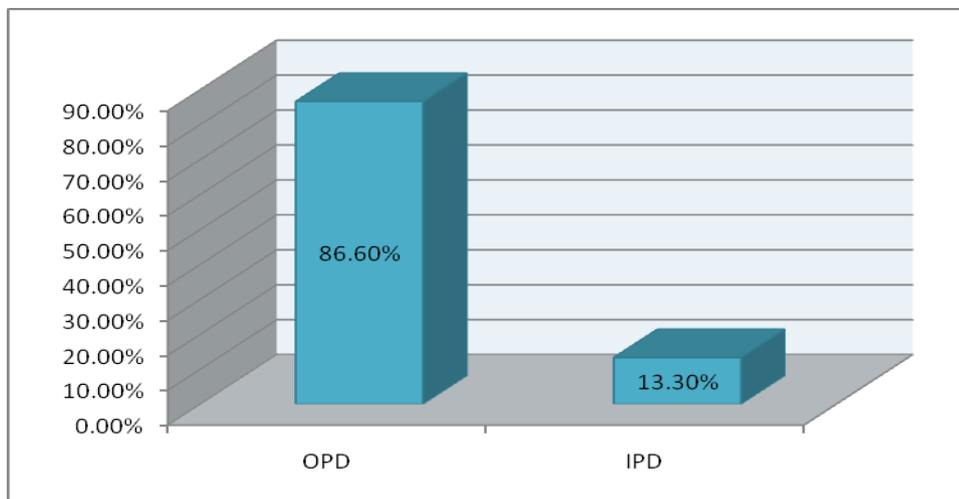


Fig. 3: Distribution of NSAIDs users in OPD & IPD

**Types of Non-Steroidal Anti-Inflammatory drugs prescribed**

During the study it was observed that Aryl acetic acid derivatives (Aceclofenac, Diclofenac) were the most frequently prescribed drugs category (52.5%) followed by paracetamol (26.6 %), ibuprofen

(10.5%), nimesulide (6.26%), lornoxicam (4%). Among the individual drugs aceclofenac was the most commonly prescribed drug (32%), followed by paracetamol (26%), ibuprofen (10.5%), and nimesulide (6.26%). (Table 4, Fig 4)

Table 4: Types of Non-steroidal anti-inflammatory drugs prescribed

Class	Drugs	No. of prescription	% prescription
Aryl acetic acid	Aceclofenac	162	32.7
	Diclofenac	98	19.72
	Total	260	52.52
Propionic acid derivative	Ibuprofen	52	10.50
Preferential COX-2 Inhibitor	Nimesulide	31	6.26
Para-aminophenol derivative	Paracetamol	132	26.6
Oxicam derivative	Lornoxicam	20	4.04
Grand total		495	100

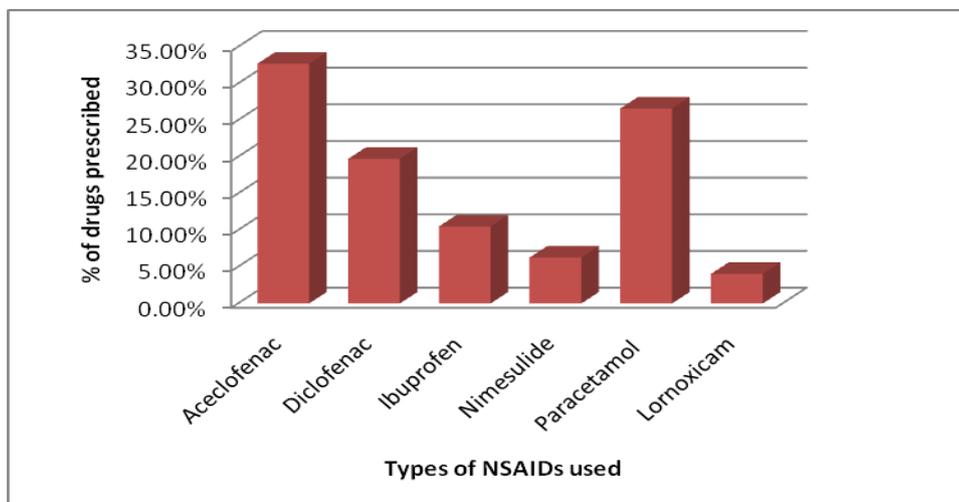


Fig. 4: Types of non-steroidal anti-inflammatory drugs prescribed

**Generic Vs Brand Name of NSAIDs**

All the prescriptions of NSAIDs users used the Brand name of NSAIDs preparations.

**Comparison between Oral Therapy Vs. Topical Therapy & Parenteral Therapy**

Table shows the distribution of non-steroidal anti-inflammatory drugs as oral, topical & parenteral therapy. Over all 81.4 % of anti-inflammatory drugs were taken by oral route and 16.3% by topical route & 2.2% of parenteral therapy. (Table 5)

**Number of NSAIDs Prescribed Per Prescription**

Average no. of non-steroidal anti-inflammatory drugs prescribed per prescription is found to be 1.65%. (Table 6)

**Formulation Prescribed to the Patients**

Prescriptions of NSAIDs users showed that total 133 patients (44.3%) received NSAIDs as monotherapy; whereas 95 patients (31.6%) were a two drug therapy, while 24% received three NSAIDs regimen (Table 7)

**Most Commonly prescribed drug as single or as combination therapy**

Prescription pattern and frequency of non-steroidal anti-inflammatory drugs prescribed for different NSAIDs user both as monotherapy and combination therapy is given in the Table 15 & 16.

Acetofenac (18.3%) was most commonly prescribed drug as monotherapy followed by, Ibuprofen (8%) Diclofenac (8.6%), Lornoxicam (5%). (Table 8) Among the combination therapy, Acetofenac+Paracetamol+Serratopeptidase was most frequently prescribed (40.6%), followed by Diclofenac+Paracetamol (15.3%), Ibuprofen + Paracetamol (11.6%), Nimesulide+Paracetamol (8.3%). (Table 9)

**PATIENT ADHERENCE**

Weekly Diary Cards for daily drug intake to monitor adherence to prescribed dosage regimen was used and criteria for non compliance was < 80% of recommended intake of prescribed medicines (Table 19). 143 (47.6%) of total patients showed a good adherence with the prescribed treatment. Adherence was found to be slightly better in females (24.3%) than in male (23.3%). (Table 10)

**Table 5: Comparison between oral therapy vs. topical therapy & Parenteral therapy**

Therapy	No. of drug	% of drug
Oral therapy	403	81.4
Topical therapy	81	16.3
Parenteral therapy	11	2.2
Total	495	100

**Table 6: Number of non-steroidal anti-inflammatory drugs prescribed per prescription**

Total no of NSAIDs/ Prescription	495
Total no of prescriptions	300
Avg. no of NSAIDs per prescription	1.65

**Table 7: NSAIDs prescribed as monotherapy and combination therapy**

Drug prescribed	No. prescription	% of prescription
Single NSAIDs (one drug)	133	44.3
Two drug	95	31.6
Three drug	72	24
Total	300	100

**Table 8: Most commonly prescribed NSAIDs as single therapy**

Name of drugs	No. of patients prescribed	% of prescribed
Acetofenac	55	18.3
Diclofenac	26	8.6
Ibuprofen	24	8
Lornoxicam	15	5
Total	120	40

**Table 9: Most commonly prescribed NSAIDs as combination therapy.**

Drugs	No. of patients	% of Prescribing
Acetofenac + Paracetamol + Serratopeptidases	122	40.6
Diclofenac + Paracetamol	46	15.3
Ibuprofen + Paracetamol	35	11.6
Nemesulide + Paracetamol	25	8.3
Total	203	67.6

**Table 10: Patients Adherence**

Patients Adherence	Male No. of patients (%)	Female No. of patients (%)	Total No. of patients (%)
< 80% (poor compliance)	82 (27%)	75 (25%)	157 (52.3%)
≥ 80% (good compliance)	70 (23.3%)	73 (24.3%)	143 (47.6%)

## DISCUSSION

To our knowledge, considering prescription drugs this is the first study providing comprehensive information on the prevalence and the pattern of NSAIDs use a population. In long term use of NSAIDs show various types of ADRs in different patients. A prescription-based survey is considered to be one of the scientific method to assess and evaluate the rationality of the prescription for observation of the drug utilization study. This observational, prospective study drew on drug use data that reflect actual clinical practice in the community.

Although most of studies have shown there are more female patients who use NSAIDs than male. Present demographic study showed that more males 157 (52%) are using NSAIDs than 143 (47%) female out of the 300 patients. Similar results have been reported in St. John's Medical College Bangalore India.<sup>9</sup> In another similar study data showed that number of females is more than males with a mean age of 53.7 yrs.<sup>10-11</sup> Because after 40 yrs female show more osteoporosis due to hormonal disturbance, where as we found a higher exposure in the women for all age groups and the indications. Moreover, our data about the relationship between older age and NSAID use were similar to those reported by other studies (Pilotto et al., 2003).<sup>12</sup>

In this study, a majority of the patients were between the age ranges of 31-40 yrs. It shows that more NSAIDs users are in 31-40 age groups. In current study most of the NSAIDs users were associated with rheumatoid arthritis 75 (25%). Literature reveals that 80% of patients have shown at least six month history of NSAIDs intake.<sup>10-11</sup>

In the present observational based study 71% of NSAIDs users were non-vegetarians, which is more in comparison to vegetarians (29%). On the basis of Smoking status, 22% were found smoker and 78% non-smoker and 9.3% of users male all were alcoholic among 300 patients.

During the study it was observed that aryl acetic acid derivative were the most commonly prescribed drugs (52.5%). Amongst aryl acetic acid derivatives Aceclofenac was the most commonly prescribed drug (32.7%) followed by Diclofenac (19.7%). An Indian study has shown the first choice of drugs were Ibuprofen, Aspirin, Diclofenac, Paracetamol.<sup>13</sup> In other study it is also reported aryl Acetic acid derivatives are most commonly used followed by Ibuprofen + Paracetamol, Piroxicam and Indomethacin.<sup>14</sup>

Para-amino phenols were the second most commonly prescribed drugs category 26.6%, followed by Nimesulide 6.2%, Ibuprofen 10% and newer Oxicam derivative Lornoxicam 4%. From this category, Paracetamol was used commonly 26.6%. A foreign study has shown that Nimesulide (35%) was the most common drugs followed by aryl acetic acids 14% and Ibuprofen 11%.<sup>11</sup> A foreign study reported that Ibuprofen is the most frequently used drug in Spain.<sup>15</sup>

In topical therapy aryl acetic acid derivative 16.3% have been more used. From this group only Diclofenac was used. A foreign study reported Diclofenac is commonly used as topical therapy.<sup>10</sup>

In our study more than 80% of the NSAIDs were prescribed via oral route and 16.3% via topical route and 2.2% via parenteral route as therapy. Topical route causes a high local concentration in cutaneous and subcutaneous area of the body with low systemic delivery, there by significantly improving therapeutic efficacy and minimizing systemic side effects.

In present study majority of the patients using NSAIDs were on combination therapy 67% and approximate 40% of patients were on monotherapy. Among the combination therapy, Aceclofenac + Paracetamol + Serratopeptidase combination was most frequently prescribed (40.6%) followed by Diclofenac + Paracetamol (15.3%), Ibuprofen + Paracetamol (11.6%), Nimesulide + Paracetamol (8.3%).

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