Determinants and effects of self-administration with NSAIDs in a tertiary care hospital of Eastern India

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Abstract

Introduction: Self-Medication is a practice common in developing countries, and accepted in society, unlike the western world. NSAIDs are responsible for the delayed diagnosis (due to suppression of clinical features), disease progression and adverse effects.
Objective: To determine the factors leading to self-administration of NSAIDs, their usage pattern and possible adverse effects. To compare NSAID's use by prescription and over the counter acquisition.
Materials and Methods: The present study investigates the determinants and effects of self-administration of NSAIDs by patients attending a tertiary care hospital during August- October 2019. The patients were interviewed regarding basic socio demographic variables, their rationale behind taking NSAIDs along with adverse effects experienced by them with a validated questionnaire. Their awareness pertaining to the drugs was also assessed.
Results: 55.2% of the population were aware about adverse drug reaction due to NSAIDs but only 17% suffered any consequence of such activity. 23% of the patients were not aware about the nature of the disease whereas 44.2% visited physician less than 1 month. Awareness regarding adverse drug reaction is more in elderly and middle aged in compare to youth. The intention to administer the drugs was relief of musculoskeletal pain (62.9%) followed by relief of headache (15.2%) followed by others. The people at the medicine shops are advisors to majority of the people administering drugs without prescription (42.9%) followed by family members (32.4%), colleagues as well as friends.
Conclusion: We found large proportion of patients taking self-prescribed NSAIDs for symptomatic relief and advice by overenthusiastic peers.

Keywords: NSAIDs, Self-medication, Over the counter, Patients, ADR.

Introduction

Non-steroidal anti-inflammatory drugs (NSAIDs) are used for their analgesic antipyretic and anti-inflammatory effects in patients with multiple medical conditions. NSAIDs, including aspirin, do not change the course of disease progression, rather are used for symptomatic relief. The primary activity of NSAIDs is to inhibit cyclooxygenase[1] (COX; prostaglandin synthase) thereby impairing the ultimate transformation of arachidonic acid[2] to prostaglandins, prostacyclin, and thromboxane.[3] Self-Medication is a common in developing countries.

The main aim of the study is to evaluate the prevalence of use of anti- inflammatory, analgesic and antipyretic form of medicines being administered by a patient without the prescription of a licensed doctor in a population group of Kolkata. It has been said that developing countries like India have a low doctor patient ratio[4] which causes patients to administer drugs oneself. The other causes are saving money, non-desire to spend in medical reasons, history of similar symptoms, socioeconomic status[5] etc. The main aim of this study is to determine all such factors.

Improper dosage of NSAIDs cause drug resistance,[6] hypertension[7] and other cardiovascular events,[8] Gastrointestinal toxicity (NSAID gastropathy),[9] anticoagulant effects,[10] Reye syndrome,[11] effects on pregnancy, renal function,[12] and both allergic and pseudo allergic reactions.

Aims and Objectives

1. To determine the factors leading to self-administration of NSAIDs, their usage pattern and possible adverse effects.
2. To compare NSAID's use by prescription and over the counter acquisition.
3. To analyze the chief complaint of the Patient at the OPD and correlate it with self- administration of NSAIDs.

Materials and Methods

A cross-sectional descriptive study was conducted at the outpatient department in the department of Medicine, ESIC Medical College, Joka after getting ethical clearance from Institutional Ethics Committee from August 11, 2019 to October 11, 2019. The outpatient department has been set up by the Government of India with the aim of providing free treatment to Insured People. It operates from Monday to Saturday, from 9 am to 4 pm with approx. 500 people visiting per day. All the people who have previously taken NSAIDs included in the study. Those who refuge to give consent and taken paracetamol are excluded from the study.

This is a descriptive cross-sectional study; hence non probability convenient sampling method was applied. On each OPD visit day, we recruited eligible study subjects after getting informed consent in the order of their appearance.

However, we calculate the minimum sample size using the formula:

$$x = Z\left(^{c}/_{100}\right)^{2} r(100\text{-}r)$$

$$n = \dfrac{2}{^{Nx}/((N\text{-}1)E + x)}$$

$$E = \mathrm{Sqrt}\big[^{(N\,-\,n)x}/_{n(N\text{-}1)}\big]$$

N is the population size, *r* is the fraction of responses that you are interested in, and *Z*(*c*/100) is the critical value for the confidence level *c*.

We shall be accepting a margin of error of 5%. As per a study conducted previously,[13] it has been seen that about 75% of the drugs sold in a pharmacy without the supervision of any registered doctor is analgesics, so accordingly we took 75 patients for our study. We took the confidence level as 95% wherein we assume that one in twenty would be answering the questionnaire in a way that would be giving a margin of error away from the true result. Using the above data and formula, we calculate the minimum sample size but we got 105 patients during the study period.

A pre-validated questionnaire consisting of three parts will be used. Socio-demographic profile of the patient age, sex, religion, marital status, monthly family income, education status, occupation. Modified Kuppuswamy[5] scale was used to derive the socioeconomic condition. The content validity of the questionnaire was checked by experts of qualitative research. The two-week test-retest reliability was checked in an initial group of 30 patients. Cronbach's alpha (0.83) proved our questionnaire as reliable and valid one.

Patients attending OPD of Medicine was interviewed using the validated questionnaire after receiving their prior consent. A subject once interviewed would not be interviewed on his/her subsequent visit to the center.

After collecting all data, data entry was done in Microsoft Office Excel. Data was organized and presented by applying principles of descriptive statistics. Descriptive statistics was summarized by Median and Interquartile range (IQR) or mean and standard error of mean(SEM). Shapiro Wilk goodness of fit test was used to assess normality. 95% confidence interval was used whenever relevant. Pearson's correlation coefficient 'r'(parametric) or Spearman's rank correlation coefficient rho (ρ)(nonparametric) were used to explore association between variables depending on nature of distribution of data. The data from questionnaire was transcribed into an excel database and analyzed by using R version 3.3.3 and RStudio version 1.0.136 (R foundation) statistical software and (language).

Prior consent form was taken from the Institution Ethics Committee before conducting the study (Evidence already submitted as it is a completed and approved ICMR project, reference ID 2019-03897). A patient consent form translated into local language was used to take informed consent of the patient before interviewing them. Anonymity and confidentiality were ensured.

Result

105 patients were included in this study by nonprobability convenient sampling method. Average age of the patients were 39.1 (12). 38.1% were female and rest were male. Majority were Hindus (89.5%). Most of the study population were married (85.7%), working, had more than 5 years of education, belonged to nuclear families having monthly income of more than Rs. 5000. 32.4% came from rural area whereas rest were urban. 43.8% did primary education and 38.1% even had done secondary education mentioned in Table 1. 55.2% of the population were aware about adverse drug reaction due to NSAIDs but only 17% suffered any consequence of such activity as mentioned in Table 2. 23% of the patients were not aware about the nature of the disease whereas 44.2% visited physician less than 1 month. 26% of the people visited clinician a year back, 97.1% population consume medication on SOS basis.73.3% of the people have been taking NSAIDs with antacids but none of them being able to specify the name of antacid or any other drug taken with the same. This is elaborately depicted in Table 3. Table 4 showed maximum number of patients had taken NSAIDs without consulting physician in musculoskeletal pain (62.9%). Awareness regarding adverse drug reaction is more in elderly and middle aged in compare to youth as depicted in figure 1. Fig. 2 clearly demonstrates the level of awareness related to NSAIDs induced ADR has been increasing with higher education from secondary level. But that is surprisingly absent following graduation. It has a direct relationship with the income of the patient and it is observed that greater income (>20000) is directly proportional to awareness about ADR due to NSAIDs vividly shown in Fig. 3.
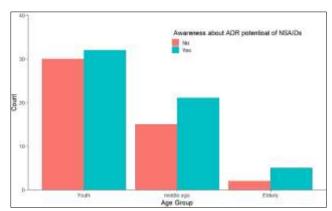

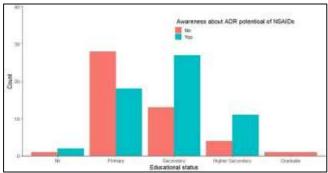**Fig. 1:** Awareness about ADR potential of NSAIDs with age

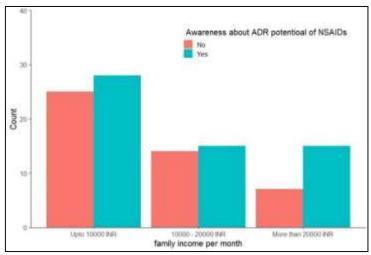**Fig. 2**: Awareness about ADR potential of NSAIDs with education

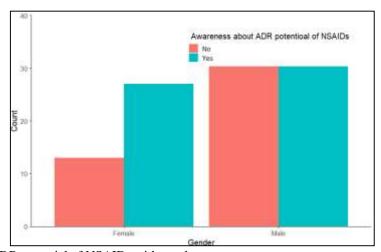**Fig. 3:** Awareness about ADR potential of NSAIDs with income

Fig. 4: Awareness about ADR potential of NSAIDs with gender

Table 1: Demographic pattern in the population taking NSAIDs

	[ALL] N=105	**N**
Age	39.1 (12.0)	105
Sex:		105
Female	40 (38.1%)	
Male	65 (61.9%)	
Religion:		105
Hindu	94 (89.5%)	
Muslim	11 (10.5%)	
Address:		105
Rural	34 (32.4%)	
Urban	68 (64.8%)	
Monthly. Family. Income	15250 (11097)	104
Education. Level:		105
Graduate	1 (0.95%)	
Higher Secondary	15 (14.3%)	
Nil	3 (2.86%)	
Primary	46 (43.8%)	
Secondary	40 (38.1%)	
Occupation:		105
Driver	1 (0.95%)	

Farmer	1 (0.95%)	
Health Worker	1 (0.95%)	
House Wife	29 (27.6%)	
Labour	45 (42.9%)	
Retired	1 (0.95%)	
Student	2 (1.90%)	
Teacher	7 (6.67%)	
Worker	18 (17.1%)	
Marital status:		105
Married	90 (85.7%)	
Unmarried	15 (14.3%)	

Table 2: Awareness of patients related to self-administration of NSAIDs

	[ALL] N=105	N
Are you aware about adverse effects of NSAIDs?		105
No	47 (44.8%)	
Yes	58 (55.2%)	
Have you suffered any adverse effects of self-administered medication?		105
No	85 (81.0%)	
Unknown	3 (2.86%)	
Yes	17 (16.2%)	
ADR skin: 0	105 (100%)	105
ADR brain:		103
No	99 (96.1%)	
Yes	4 (3.88%)	
ADR digestive:		103
No	94 (91.3%)	
Yes	9 (8.74%)	
ADR heart:		103
No	100 (97.1%)	
Yes	3 (2.91%)	
ADR genito-urinary:		103
No	102 (99.0%)	
Yes	1 (0.97%)	
ADR others: 0	105 (100%)	105
Are you agreeing, self-administration actually injurious to health?		105
No	5 (4.76%)	
Unknown	3 (2.86%)	
Yes	97 (92.4%)	
What is your perception about effectiveness of self-administration?		105
Economically effective	19 (18.1%)	
Effective for both	50 (47.6%)	
Effective for ill health	36 (34.3%)	

Table 3: NSAIDs intake and interaction with physician

	[ALL] N=105	N
Type of intake:		105
I take this medication regularly	3 (2.86%)	
I take this only when required	102 (97.1%)	
Last physician visit:		105
1 to 3 month	8 (7.62%)	
3 to 6 month	18 (17.1%)	
6 to 12 months	6 (5.71%)	
less than 1 month	47 (44.8%)	
more than 12 months	26 (24.8%)	
Question 1: Are you aware about your nature of illness		105

Not Exactly	41 (39.0%)	
No	23 (21.9%)	
Yes	41 (39.0%)	
Question 2: What factors inhibited you to consult with physician?		105
It takes a long time to visit the doctor	17 (16.2%)	
Monetary Reasons	27 (25.7%)	
No satisfactory previous consultation	5 (4.76%)	
Not taking seriously	15 (14.3%)	
Physician Prescribed same medicine repeatedly	10 (9.52%)	
You perceived it is safe	31 (29.5%)	
question_3: Is there any social impetus upon you to take medicines by self?		105
Colleagues	15 (14.3%)	
Family Member	34 (32.4%)	
Friend	11 (10.5%)	
Medicine shop	45 (42.9%)	
Question 4: Did you take antacids/equivalents with NSAIDs?		105
No	28 (26.7%)	
Yes	77 (73.3%)	
Question 5: If yes, specify type of medication		105
Not available	82 (78.1%)	
Omeprazole	8 (7.62%)	
Pantoprazole	9 (8.57%)	
Pantoprazole with domperidone	4 (3.81%)	
Ranitidine	1 (0.95%)	
Ranitidine with domperidone	1 (0.95%)	
Q6: Did you concurrently take any other medication with NSAIDs by self?		105
No	103 (98.1%)	
Yes	2 (1.90%)	
Question 7: If yes, specify type		105
Not available	103 (98.1%)	
Clindamycin	1 (0.95%)	
Diabetes medication	1 (0.95%)	

Table 4: Causes of self-administration of NSAIDs

	[ALL] N=105	N
Relief of fever		105
No	96 (91.4%)	
Yes	9 (8.57%)	
Relief of musculoskeletal pain		105
No	39 (37.1%)	
Yes	66 (62.9%)	
Relief of headache		105
No	89 (84.8%)	
Yes	16 (15.2%)	
Relief of dysmenorrhea		105
No	102 (97.1%)	
Yes	3 (2.86%)	
injury:		105
No	102 (97.1%)	
Yes	3 (2.86%)	
cough: 0	105 (100%)	105
others:		105
No	103 (98.1%)	
knee pain	1 (0.95%)	
Tooth	1 (0.95%)	

Discussion

Inappropriate use of medication may have a dangerous consequence not only in elderly patient. It has been said that developing countries like India have a low doctor patient ratio which causes patients to administer drugs oneself.[2] The other causes may be to save money, history of similar symptom etc. As per a study conducted previously,[13] it has been seen that about 75% of the drugs sold in a pharmacy without the supervision of any registered doctor is analgesics. Studies have shown that improper dosage of NSAIDs cause drug resistance,[6] hypertension[7] and other cardiovascular events,[8] Gastrointestinal toxicity (NSAID gastropathy),[9] anticoagulant effects,[10] Reye syndrome,[11] and effects on pregnancy, renal function.[12]

In our study population older age groups as well as youth self-administered NSAIDS of relieving musculoskeletal pain and the same was observed in a study on a population in Mexico by Fernando et al.[15]

However, it is also important to note self- medication is a growing phenomenon. Few studies have investigated the association between self-medication and socioeconomic factors. A Danish survey demonstrated social differences in the pattern of use of prescription drugs. In our study we have excluded prescription drugs from our design and hence tried to find out an association between awareness of adverse drug reaction (ADR) with education, financial conditions and other parameters. But a survey conducted in a Spanish study found a significant association between self- medications and higher level of education, sex, lower age and smoking habit.[14,15] In our study we also found a significant association between awareness about NSAIDs induced ADR and education (P value 0.01). Fisher exact test was carried out to find out the association between the two. Most of our population were male and came from urban area, at least having secondary education. Elderly population in our study were more aware in comparison to youth in relation to ADR associated with NSAIDs.

Conclusion

While a multitude of factors might be contributing to autonomous administration of NSAIDs, the perception of innocuous nature of the drug is the predominant justification. In the present study, the level of awareness of adverse drug reaction was not education dependent and increased with age. An association was found between the indiscriminate use of NSAIDs and adverse drug reactions. Demerits of self-medication should be percolated in the community so that people become aware about grave consequences of over the counter medication.

Source of Funding
None.

Conflict of Interest
Nil.

Declaration
It is a completed ICMR project with reference ID 2019-

03897 by Mr. Sumanta Majumdar, (6th Semester MBBS student).

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