



IJMPS
Section: Pharmaceutical
Sciences

SJIF (2020): 6.586



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Pattern of Use of Non-Steroidal Anti-Inflammatory Drugs in Rural Population, Kerala

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ABSTRACT

Introduction: In India, though studies regarding NSAIDs were conducted, prevalence of its use and its impact on general health is largely lacking. As the prevalence of unmonitored analgesic and NSAID use is rising, it is imperative to assess the pattern of NSAID use and its associated factors.

Materials and Methods: This is a cross sectional, questionnaire-based survey conducted over a period of 6 months in the rural population of Kerala, India. The data was collected with the aid of a Google form. All the data were documented and analysed based on a standard protocol.

Results: The prevalence of NSAID use among the 608 participants was found to be 43.4%. The prevalence of regular NSAID use was found to be 17.43%. It was found that females used NSAIDs more than the males (49.4%). Regular NSAID use was also found to be higher in the female population (19.9%). Diclofenac (27.6%) and mefenamic acid (24.2%) were the most commonly used NSAIDs. Headache was the major indication (29.9%) for which these drugs were taken.

Conclusion: The study analysed the pattern of NSAID use among the rural population of Kerala. The results obtained from the study is indicating to the negligent use of NSAIDs despite being aware of the possible adverse outcomes of its use by the population. This shows that the knowledge about the safe use of NSAIDs is yet to be inculcated in the society.

Keywords: Adverse effect, Analgesic, Attitude, Practice, Prevalence, Regular use

INTRODUCTION

Pain being an unpleasant sensory feeling that causes discomfort to the individual is relieved by the use of analgesics. Analgesics assuage the pain and suffering associated with a myriad of disease conditions. It is purported to be the most recurrently used non-prescriptions well as prescription medications.¹ Analgesic use is mostly related to the general pain, mental and somatic health status. It is further modified along with sociodemographic factors and life style.² The over the counter (OTC) use of analgesics is mainly associated with chronic pain, physical inactivity and is most prevalent tendency in female population. The concern of inflating OTC analgesic use and a general escalation in the prescription of analgesics for gratuitous purposes are existent.³ The suitability of analgesics for OTC use is an ongoing debate where the deliberate and inadvertent drug intoxications, drug interactions and occurrence of adverse drug reactions are constantly conferred upon.⁴

Though analgesics does not cure the root cause of the disease, there seems to be a drastic increase in the use of analgesics in previous three decades in developing countries.⁵ Although there are a profound number of analgesics used globally, NSAIDs remain the prominent analgesics used in the medical practice to alleviate pain. The US NHIS of 2005 and 2010 reports that the NSAID use has increased 41 % in the short time duration of five years and that of aspirin alone has increased 57%.⁶ The first ever reported study of prevalence and related factors of NSAID use in Thailand reported prevalence of NSAID use as 31.1 %.⁷

NSAIDs like acetyl salicylic acid, diclofenac and ibuprofen forms the analgesics of prime importance and wide usage according to National List of Essential Medicines of India.⁸ The interim analysis conducted in India shows that though there are other analgesics that could be prescribed, NSAIDs are often irrationally and exaggeratedly prescribed and equally taken by the public without prior consent from their

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ISSN: 2231-2188 (Print)

ISSN: 2231-685X (Online)

Received: 08.07.2022

Revised: 23.07.2022

Accepted: 30.07.2022

Published: 22.08.2022

physician.⁹ These make the first choice of drugs prescribed by the physicians and demonstrate high efficiency in the management of pain associated with many musculoskeletal disorders and inflammatory disorders including ankylosing spondylitis, gout, arthritis (osteoarthritis, reactive arthritis, rheumatoid arthritis and psoriatic arthritis) and joint injuries. It is recurrently used in the management of pain caused by headaches, menstrual cramps, muscle cramps and dental procedures.¹⁰

Although aspirin as well as other NSAIDs demonstrate a wide array of benefits, they are also professed to cause various adverse effects.¹¹ NSAIDs such as Aspirin and ibuprofen can lead to potentially serious side effects such as Gastrointestinal (GI) inflammation and ulceration.¹² Selective COX 2 (Cyclooxygenase) inhibitors like Celecoxib and Etoricoxib have less GI adverse effects as compared to other NSAIDs. Risk of GI complications is about four times in NSAIDs users compared to non-users. All the NSAIDs manifest gastrointestinal side effects differently. While Ibuprofen and diclofenac forms the lower risk category, Aspirin and naproxen are deemed to be of intermediate risk. Piroxicam and ketoprofen shows higher risk of developing gastrointestinal events.¹³ Mechanism of GI damage induced by NSAIDs inhibition of COX 1 in gastric epithelial cells leading to decreased production of gastro mucosal protective prostaglandins especially PGI₂ and PGE₂.¹⁴

Placebo-controlled trials of three structurally similar compounds showed that celecoxib, valdecoxib(withdrawn), rofecoxib(withdrawn) revealed an increase in incidence of MI, stroke, thrombosis.^{15,16} NSAIDs and COX-2 inhibitors are associated with renal and reno-vascular adverse events. It usually occurs in chronic users of NSAIDs.¹⁴

Despite the public health relevance of NSAID use, studies on the prevalence of use of these drugs and its impact on the community health is largely lacking. NSAID use in general population should be strictly monitored with special emphasis on OTC use, occurrence of adverse events and its interaction with other OTC products, as the self-medication practices have risen to a greater extent in the COVID 19 pandemic situation owing to the repeated lockdowns and a general fear to approach a health care facility. Since it is a class of drug with high concurrent relevance and often irrational use by the general public for self-medication, it is imperative to understand and evaluate its adverse effects on long term and intermittent use.

METHODS

A cross sectional study was conducted as an “online questionnaire survey” over a period of six months in the rural areas of Kerala. Individuals aged eighteen and above were made part of the survey. All the individuals who were

illiterate, unable to communicate and who used topical preparations of NSAIDs were excluded from the survey.

The Google form was created in four sections:

The first section consisted of online consent from the study subjects. The accompanying section was for collection of patient demographics and contact information. **Socio economic data** of the study participants was collected using **Kuppuswamy’ scale** (Occupation, Education, Monthly family Income). The next section formed the heart of the survey which was intended to collect information about prevalence and patterns of NSAIDs use among rural population.

RESULTS

Out of the 613 entries obtained, 608 entries were made a part of the survey. There were 5 repeated entries which were sorted and rejected to assure the reliability of data. Characteristics of the rural population participated in the survey is described in Table 1. Approximately 40% of the participants were males. 63.4% of the participants constituted of the females. Most of the subjects were aged between 20 and 25. Mean age of the subjects was 30.135 ± 13.1828 . Maximum number of NSAID users were from the Southern district of Pathanamthitta and Northern district of Kannur. Occupation was scored and categorized based on Kuppuswamy’s scale along with the education and monthly family income to form socio economic classes of participants (Table 2). 59% of the individuals participated in the survey were unemployed. Inclusion of vast majority of students (60%), who were the main participants of this survey, in this category led to the rise in number of unemployed populations. Retired personnel were also categorized under unemployment.

The prevalence of NSAID use among 608 participant was found to be 43.4%. The prevalence of regular NSAID use was found to be 17.4%. Females used NSAIDs more than the males (49.4%). Regular NSAID use was also found to be higher in female population (19.9%). 39.4% of the total NSAID users were graduates and 4 of the total 5 individuals with middle school education were NSAID users.

37.5% of the NSAID using population (N=264) used NSAID for more than a year. Diclofenac (27.6%) and mefenemic acid (24.2%) were the most commonly used NSAIDs (Figure .1). A total of 21 subjects were using combination of NSAIDs (8.6%). Diclofenac, Aceclofenac and Mefenemic acid were the drugs widely used in combinations. Headache was the major indication (29.9%) for which these drugs were taken (Figure.2). 54.5% of the users (N=264) took NSAID as per the direction and prescription of a practicing physician. 51.1% of the NSAID users relayed on the community pharmacies to obtain the medications. 37.5% of the users

obtained the medication from the hospital pharmacy. 30 of them relayed on other sources (Table 3). 8.3% of the NSAID users reported presence of GI side effects. 40.9% of the subjects with the ADR managed the symptoms by taking home remedies (Table 4).

The knowledge, attitude and practices survey which enquired about the knowledge of the rural population about NSAID use found that subjects had meagre knowledge about the use of these medications especially in pregnancy (62.3%) and with blood thinners (anticoagulants) (46.8%) (Table 5) (Fig 3). General knowledge regarding the consumption of NSAIDs was also enquired and the responses provided showed a general lack of awareness among the population (Table. 6).

DISCUSSION

Our study was focused on the prevalence and general pattern of NSAID use among the rural population where it was obvious that the NSAID use is quite prevalent among the selected population and that the knowledge of these individuals on its use was limited. Use of these analgesics were largely dependent on sociodemographic factors and the findings were mostly consistent with major studies conducted over years in various countries.^{4,5,6} The prominence of the female population participation in our study is comparable to the participant ratio of the study conducted by Pongsum Luanghirun et al. in Thailand which was focused on prevalence of NSAID use and factors associated with it. There of the 771 participants who became a part of the survey, 282 (36.6%) were males and 489 (63.4%) were females. The eldest participant in our study was aged 88 and the presence of a large number of younger populations in the study was in great contrast to their population participation were majority of them were aged above 40.⁷ Occupational distribution among gender shows that of all the males participated (222), 50% (111) of them are unemployed. It may be attributed to the increased number of male participants who were retired and is leading a life free of occupational distress. The percentage of unemployment in female population was found to be 64.7%. As compared to males, females are more likely to hold a professional occupation (16%). This may be owing to the increase in higher education among women of Kerala (50%) as per data collected from AISHE and census of 2011 by MHRD.¹⁷

Prevalence of NSAID in the Thai study was 31.1% which was slightly lesser compared to our study (43.4%). The geographical, socioeconomic and lifestyle changes along with the change in time might have influenced this regional differences.⁷ Chi square test was used to correlate the prevalence of NSAID use to the gender. There exists a high correlation with these two set of data with a p value of

0.000 showing its high significance and it was found that the female population has a greater inclination to the use of these drugs. Of the total NSAID users' males who use NSAIDs was 73 (27.6%). And female users were 72.3% of total NSAID users. In the study conducted in Germany, the use of NSAIDs like diclofenac (4.4%), ibuprofen (10.3%) and naproxen (0.2%) were found to be higher in females than in their respective male counterparts (4.3%), (5.7%), (0.1%).⁴ On comparing different age groups with prevalence of NSAID use, it was clear that there is high prevalence of NSAID use among the age group above 60. Though compared to the whole NSAID user population (264) the percentage of subjects above 60 using NSAIDs is low (5.3%) (owing to the minimal participation of individuals belonging to the age group), the Percentage of subjects using NSAIDs per this age group is high (66.66%). Higher percentage of younger population [<20 (47.3%), 20-25 (44.6%), 26-30 (46%)] was also found to be using NSAIDs. According to the Norwegian survey (HUNT 3), 24% of the study population belonging to the age group of 19 and 39 were found to be NSAID users. In contrast to our data NSAID use among the elderly population was found to be 4.9%.³

Prevalence of regular NSAID use was found out by asking the participants if they were taking NSAIDs for at least three times a week for the past 3 months. Prevalence rate of regular NSAID use thus was found to be 17.4%. That is 106 out of 608 subjects were regular NSAID users which is far too greater compared to the prevalence percentage in the study conducted in Thailand (7.4%).⁷ Prevalence of regular NSAID use in U.S was found to be 12.1% by the 2010 NHS.⁶ Prevalence study of regular use among both genders shows that female regular NSAID users is 77 which makes 19.9% of total female population (386) and that among males is 29 making 13% of the total male population (222) participated in the survey. It is far too greater a percentage compared to the Thailand study were out of 57 participants who were regular users of NSAID, 15 (5.3%) were males and 42 (8.6%) were females.⁷ The U.S study shows that 20.8% of males and 17.3% of females were regular users of aspirin.⁶ The correlation of gender to regular NSAID use by Spearman correlation, shows a p value of 0.029 showing significance of the correlated data. Comparing prevalence of NSAID use with different age groups shows that age group above 60 tend to use NSAIDs regularly making 52.3% of the corresponding population to be regular users. Even though the age group below 20 showed high prevalence of NSAID use (47.3%), it is reassuring to know that the regular use is not seen in this age group.

A total of 21 subject were using combination of NSAIDs which is 8.6% of responders. Diclofenac, Aceclofenac and mefenemic acid were the drugs most commonly used in combination. The study conducted in Germany reported the combination use of NSAIDs to be 6% and the commonly

used combinations as diclofenac with aspirin or ibuprofen. 4.9% used paracetamol in combination with an NSAID.⁴ HUNT 3 study in Norway reported use of 2 NSAIDs among 385 subjects.³ The major indication for NSAID use was headache but the use of NSAIDs to maintain menstrual cramps among women was equally high. Of the total female population 19.17% of them are taking NSAIDs to manage the cramps. Correlation of the types of NSAIDs use to its indication by Spearman's correlation was found to be of p value 0.000 showing high significance. When comparing the indication with NSAIDs used, mefenemic acid for menstrual pain (43) is the most commonly used NSAID and indication. 28 respondents used diclofenac for general pain .15 of them use it for the management of head ache. There were 8 participants who used ibuprofen for dental pain.

30 subjects who solely depended on NSAIDs from sources other than hospital pharmacy and community pharmacy obtained it from doctor's clinic (9) and PHCs (21). Thailand study shows that 72.5% of non-regular NSAID users and 27.5% of regular NSAID users depended on the hospital pharmacy for obtaining the NSAIDs. Similarly, 82.2% of non-regular users and 17.8 % of the regular NSAID users obtained NSAIDs from other sources.⁷

Knowledge, attitude, practice survey was designed to assess the knowledge of the respondents about particular aspects of NSAID use. It gives insight into the practices followed by the participants on certain occasions and attitude of general public related to NSAID use. 5 questions were on the knowledge about the safety of NSAIDs and 4 questions were on the knowledge about safe consumption of NSAIDs. On enquiring the respondents whether the NSAID use in pregnancy was safe, 379 (62.3%) of them answered that the use of NSAIDs in pregnancy was safe. This shows the lack of knowledge of the public about embryo, fetal and the neonatal adverse effects of these drugs. It also points towards the fact that these subjects are unaware of the fact that NSAIDs can cause miscarriages and malformations when consumed in the early stages of pregnancy.¹⁸ NSAIDs like aspirin is a pregnancy category C drug with increased perinatal mortality, bleeding and teratogenic effects. Ibuprofen is a pregnancy category B drug but is category D in the third trimester with ample evidence of fetal risk including pulmonary hypertension and ductus arteriosus constriction.¹⁹ It was relieving to know, as the alcohol consumption in copious amount along with NSAID use increase the risk of upper GI bleed, that compared to the knowledge about use of NSAIDs in pregnancy, the knowledge about use of alcohol with NSAIDs was more ingrained in these population.

385 (63.3%) of the respondents answered that they were aware of the side effects caused by NSAIDs on their prolonged use. Glomerular and interstitial diseases, reversible membranous nephropathy and nephritic syndrome are precipitated on long

term use of NSAIDs.^{20,21} There were 108 subject who did not answer this question, either because they were not sure about the answer or because of disinterest. If the cause is former, it increases the percentage of population actually not aware of the renal injury caused by the long-term use of these drugs.

Current study was useful in collating the factors that directly affected the NSAID use in the rural population of the area and assessing the basic knowledge of the population about this drug use. The factors affecting the prevalence of NSAID use directly were found to be gender(0.000) and monthly family income(0.008) and that of the regular NSAID use was found to be gender alone(0.029). Limitation of the study was that the study was an online survey and the face to face element which makes us understand the pulse of participant perception was lost due to the pandemic situation. The real advantage of the study is that it is one of the rare population based study in India that assess the NSAID use among the rural population and gives an insight into the minds of people regarding this drug use. This study thus is relevant in concurrent scenario where the self-medication is exponentially increasing and people are searching for fastest routes to alleviate minor ailments without proper consultation with a health professional.

CONCLUSION

The results obtained from the study is indicating to the negligent use of NSAIDs despite being aware of the possible adverse outcomes of its use by the population. This shows that the knowledge about the use of NSAIDs is yet to be inculcated in the society The promotion of pharmacy service practices can yield better results. Proper and systematic patient counselling and safety demonstration programs might be useful in developing the societal knowledge and thus safe use of NSAIDs. The distribution of patient information leaflets and organizing patient awareness campaigns might render useful towards this endeavour. The study is a staunch reminder of the fact that educating the rural population might alone will not attenuate the NSAID use. Coercing the prescribing physicians to curb the prescription of NSAIDs to absolute minimum and only, when necessary, is as important as patient awareness programmes.

ACKNOWLEDGEMENT

The authors are truly grateful to their peers who held an indispensable role in data collection and the College management for their immense support.

Source of funding:

There was no funding for the study

Conflict of Interest:

Authors declare no conflict of interest

Authors' Contribution:

1. Annmaria Tom –Data collection, Statistical work up and manuscript writing
2. Hima Sabu-Data collection, Manuscript writing
3. Kiron S S-Statistical work up, Final approval and editing

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Table 1: Characteristics of population

Characteristics	Total	No. of NSAID users	No. of regular NSAID users
Sex			
Male	222	73	29
Female	386	191	77
Age			
<20	19	9	1
20-25	354	158	50
26-30	76	35	13
31-40	41	11	6
41-60	97	37	25
61-90	21	14	10
<20	19	9	1
District			

Table 1: (Continued)

Characteristics	Total	No. of NSAID users	No. of regular NSAID users
Trivandrum	47	15	5
Kollam	37	14	9
Pathanamthitta	52	30	9
Idukki	37	15	8
Kottayam	36	13	5
Alappuzha	40	15	4
Ernakulam	39	24	8
Thrissur	71	29	12
Palakkad	32	11	7
Malappuram	31	18	10
Kozhikode	50	19	8
Wayanad	31	13	2
Kannur	66	30	11
Kasaragod	39	18	8

Table 2: Socioeconomic classification of population based on Kuppuswamy's scale

Socioeconomic Class	Total	No. of NSAID users	No. of regular NSAID users
UPPER (26-29)	46	20	12
UPPER MIDDLE (16-25)	192	99	41
MIDDLE/LOWER MIDDLE (11-15)	186	81	22
LOWER/UPPER LOWER (5-10)	184	64	31
LOWER (<5)	0	0	0

Table 3: NSAID use evaluation

	Frequency(N=608)	Percentage
NSAID use		
Yes	264	43.4
No	344	56.5
Regular NSAID use		
Yes	106	17.4
No	502	82.5
Duration of NSAID use		
<1 year	151	24.8
>1 year	99	16.2
Source of knowledge about NSAIDs		
Doctor's prescription	144	23.6
Internet search	12	1.9
Pharmacist suggestion	53	8.7
Suggestions from relatives and friends	62	10.1
Sources of NSAIDS		

Table 3: (Continued)

	Frequency(N=608)	Percentage
Hospital Pharmacy	99	16.2
Community Pharmacy	135	22.2
Others	30	4.9

Table 4: ADR profile of NSAIDs among users

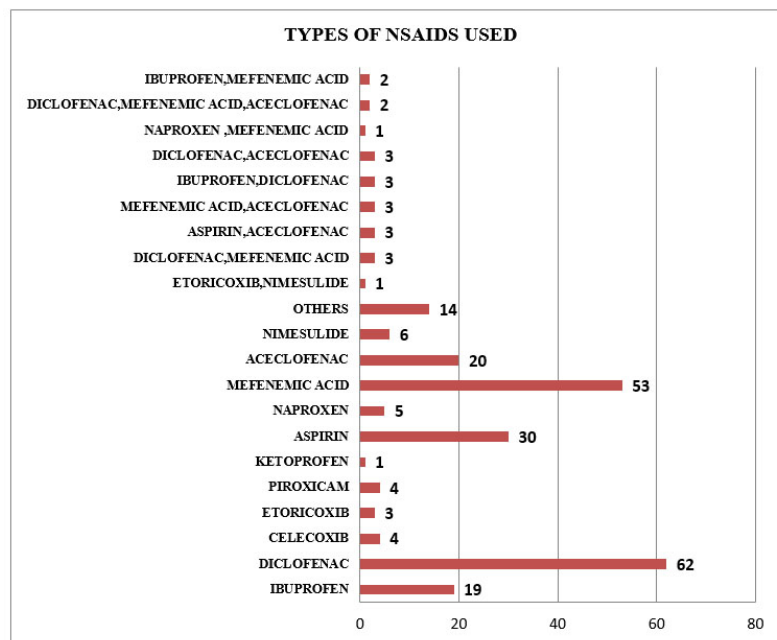
	Frequency(N=264)	Percentage
Presence of ADR		
Yes	22	8.3
No	242	91.6
Management of ADR		
Home remedies	9	3.4
Took advice from physician	8	3.0
Took advice from pharmacist	2	0.7
Reported to the medical practitioner	3	1.1

Table 5: Knowledge about safety of NSAIDs

Questions	Response	Frequency(N=608)	Percentage
Knowledge of safety in taking these medications during pregnancy.	Yes	379	62.3
	No	65	10.7
	Do not know	51	8.4
	Not responded	113	18.6
Knowledge of safety of taking these medications with alcohol	Yes	27	4.4
	No	414	68.1
	Do not know	63	10.4
	Not responded	104	17.1
Knowledge about side effects of long-term use	Yes	333	54.8
	No	44	7.2
	Do not know	125	20.6
	Not responded	106	17.4
Knowledge about kidney injury on long term use	Yes	385	63.3
	No	56	9.2
	Do not know	59	9.7
	Not responded	108	17.8
Knowledge about safety in taking these medications with blood thinners	Yes	29	4.8
	No	175	28.8
	Do not know	285	46.9
	Not responded	119	19.5

Table 6: Knowledge about safe consumption of NSAIDs

Questions	Response	Frequency(N=608)	Percentage
Knowledge on consumption of NSAIDs along with food	With Food	388	63.8
	Without food	92	15.1
	Not responded	128	21.0
Knowledge on duration of safe consumption of NSAIDs	10 days	170	27.9
	10-30 days	43	7.0
	>30 days	9	1.5
	Do not know	265	43.5
	Not responded	121	20.1
Knowledge on safety of simultaneous consumption of more than one NSAID	Safe	45	7.4
	Not safe	252	41.4
	Do not know	200	33.0
	Not responded	111	18.2
Knowledge on what to do when missed a dose	Keep missing the dose	23	3.8
	Take missed dose immediately as you remember	161	26.5
	Skip dose and wait for the next dose	229	37.7
	Inform the prescribed physician	53	8.7
	Not responded	142	23.3

**Figure 1: Types and combinations of NSAIDs used**

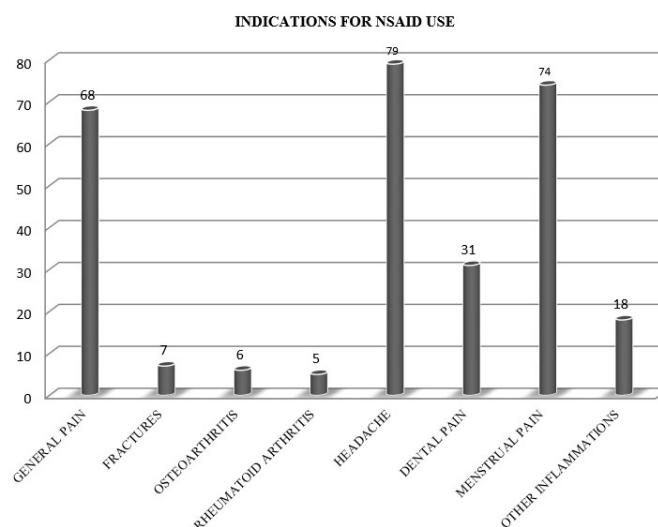


Figure 2: Indications of NSAID use.

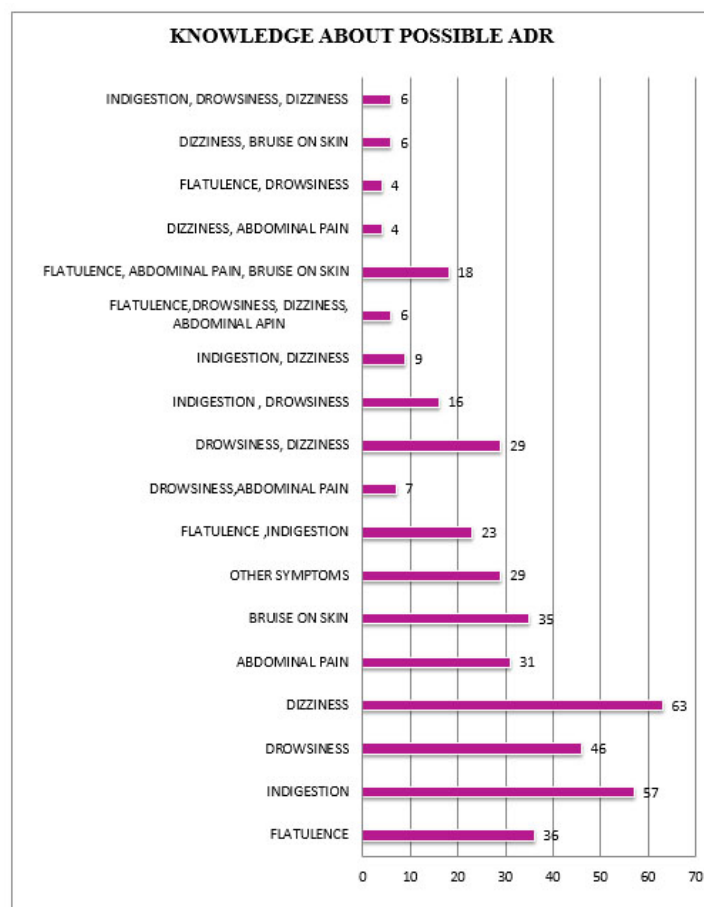


Figure 3: Knowledge about NSAID use.