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Research Article

Misuse of prescription analgesics and predictors of analgesic misuse among urban young adults of Sikkim, India

D Dass[1*], B. Khandelwal[2]

[1]Department of Pharmacology, Sikkim Manipal Institute of Medical Sciences, Gangtok, Sikkim, India
[2]Department of Medicine, Central Referral Hospital and Sikkim Manipal Institute of Medical Sciences, Gangtok, Sikkim,India

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ABSTRACT

Background: Non-steroid anti-inflammatory drugs (NSAIDs) are the most widely used analgesics and are available without prescription. NSAIDs can be acquired outside of pharmacies, the increase in NSAID consumption and the decrease in professional counseling (by physicians and pharmacists) may pose a serious risk for a substantial increase in adverse effect occurrences. Literature documents several factors affecting the possibility of analgesic misuse such as health status, the frequency and the manner of using analgesics, education and literacy skills (knowledge of safe usage, dosing, combining with other drugs etc.).**Aim:** The aim of this study was to recognize and describe the important predictive factors of the misuse of prescription analgesics among urban young adults of either sex in Sikkim, India.
Methods: A pre devised validated case record form was administered to n=700 subjects. Data was statistically analyzed using Statistical Package of Social Sciences software. **Results:** Statistically significant results were obtained for pain in the past 30 days (χ^2 = 23.282, df=1, P<0.001), source of income (χ^2 = 7.326, df=2, P=0.026), smoking in the past 30 days (χ^2 = 14.430, df=2, P=0.001), body mass index (χ^2 = 140.224, df=2, P<0.001) and depression (χ^2 = 13.811, df=2, P=0.001).**Conclusion:** Several socio-demographic and lifestyle factors along with smoking in the past one month were associated with a continuous regular analgesic misuse of method was carried out utilizing ICH-guidelines. The described HPLC method method was successfully for the analysis of pharmaceutical formulations containing dosage form.

Introduction

Non-steroidal anti-inflammatory drugs (NSAIDs) are one of the most commonly used medications worldwide without prescription and as Over the Counter (OTC). The huge availability of products containing an NSAID, combined with a lack of recognition and understanding of NSAIDs, can increase the potential of consumers to exceed the recommended NSAID dosage, which can cause serious side effects. Appropriate physician and consumer education regarding the use of NSAIDs can help prevent misuse of NSAIDs. Recent patterns of NSAID use and perceptions about NSAIDs are necessary to develop targeted educational programs. The aim of this study was to recognize and describe the important predictive factors of the misuse of prescription analgesics among urban young adults of Sikkim, India. NSAIDs are not well recognized by generic or brand names and many respondents are unaware or unconcerned about its potential side effects. NSAIDs are widely used and often used in a manner that increases the risk of serious side effects. [1]The literature refers that in countries where prescription NSAIDs can be acquired outside of pharmacies, the increase in NSAID consumption and the decrease in professional counselling (by physicians and pharmacists) may pose a serious risk for a substantial increase in adverse effect occurrences. [2] NSAID use patterns have been documented for various populations. In Italy, NSAID usage is common and more prevalent in the elderly and in females. [3] NSAID adverse effects have been extensively surveyed, particularly in the last decade, and in high risk patients, including the elderly.

***Corresponding Author: D Dass,** Department of Pharmacology, Sikkim Manipal Institute of Medical Sciences, Gangtok, Sikkim, India

[4] There are numerous factors inherent to the elderly, such as co-morbidities and polypharmacy, make the aged highly susceptible to develop drug related problems. [5] The authors understand the misuse of analgesics as a situation in which patients use medicines in a manner contrary to their purpose and when they incorrectly combine medicines with other drugs and substances, overdose or consume them contrary to professional recommendations. Factors affecting the possibility of analgesic misuse are health status, the frequency and the manner of using analgesics, education and literacy skills (knowledge of safe usage, dosing, combining with other drugs etc.). Analgesic misuse was defined in this study as any current (past 30 days) use of analgesics (greater than or equal to 10 doses/month) for indications other than everyday kind of pain (e.g., minor headache, sprain, toothache, pre-menstrual syndrome) without medical advice. [6-9]

Materials and Methods

Selection of study subjects: In this study only young adults (15 – 40 years of age) of either sex were enrolled as participants as this population were less likely to have co-morbid age-related chronic medical conditions requiring regular analgesic use; more likely to develop adverse consequences of regular analgesic use like gastrointestinal and renal adverse events as well as dependence over their lifetime; and this population was the best group for preventive measures.

Sampling Method & Size: Current population of Gangtok is approximately 98,658, [10] i.e., approximately 1,00,000. According to current population pyramid of India approximately 35% of the total population belongs to the age group of 15 – 40 years. [11] Therefore, in Gangtok, an approximate 35,000 people are expected to be in the age group of 15 – 40. Prevalence of regular analgesic use in age groups above 14 years has been reported in the range of 7.2 to 34.8% in European studies. Therefore, considering a younger age group of our study population (15 – 40 years) we assume an estimated prevalence of 5% analgesic misuse with an acceptable lower limit of 2% in both rural and urban sites. To detect this prevalence at a 95% confidence interval the study enrolled n=700 subjects at the urban Gangtok site. Further stratification according to age groups and gender was carried out during recruitment and stratification was adjusted according to actual percentage of population according to gender and age groups (15 – 20 years, 21 – 30 years and 31 – 40 years).The sampling strategy involved identification of sampling locations in each site. Sampling locations mostly included schools (age group 15 – 17 years), colleges (age group 18 – 22 years) and households where people in the age group of 15 – 40 years commonly aggregate and live. The study did not involve only a household survey, but assumed a more ethnographic approach. Any subject satisfying the age criteria for inclusion was eligible for the study. To minimize the uncertainty of data and to make the sample reliable, the authors have tried to maximize its resemblance to the population's characteristic by selecting participants by specified attributes: sex, age and level of education. In our study, the median age of participants was 28 years. Referring to the most important socio-demographic factors (sex and median age), the authors' sample is representative or approximate to the representative group.

Instruments: The source document was a validated case record form constituting the following:

- A generic socio-demographics section (e.g., age, gender, education, ethnicity etc.), which is a 21-item questionnaire including questions on alcohol use and smoking.
- A generic analgesic misuse questionnaire, comprising measures of non-steroidal and opioid analgesic use without medical advice, which is a 21-item questionnaire including information on treatment of pain and ease of availability of analgesics.
- Brief Pain Inventory is a standardized instrument for assessment of pain. Brief Pain Inventory (BPI) is a 9-item instrument assessing pain in different domains of functionality from a participant's perspective. It has been reported that BPI satisfies most key recommendations outlined in the draft guidance for assessing a pain-reduction treatment effect. The draft guideline was recommended in 2006 by the United States Food and Drug Administration (FDA) on the use of patient-reported outcomes (PRO) Measures in Medical Product Development to Support Labeling Claims. This draft guidance outlines psychometric aspects that should be considered when designing a PRO measure, including conceptual framework, content validity, construct validity, reliability, and the ability to detect clinically meaningful score changes. [12]
- SF – 36, quality of life questionnaire, which is an 11-item standardized instrument for assessment of quality of life in different domains. Considerable evidence was found for the reliability of the SF-36 (Cronbach's alpha greater than 0.85, reliability coefficient greater than 0.75 for all dimensions except social functioning) and for construct validity in terms of distinguishing between groups with expected health differences. The SF-36 was able to detect low levels of ill health. The SF-36 was reported as a promising new instrument for measuring health perception in a general population. It is easy to use, acceptable to patients and fulfils stringent criteria of reliability and validity. [13]

Ethical Issues: The study consisted of only interviews and subsequent data analysis from questionnaires and did not involve any patient contact, medical, behavioral, therapeutic or instrumental intervention. The study protocol, instruments/questionnaire, informed consent was duly approved by Institutional Ethics Committee (IEC).

Design and Study Sites: The study was a cross-sectional general population survey. Proposed study site included an urban area in East Sikkim. The selected urban site was Gangtok and its surroundings, East Sikkim, the most

important city in Sikkim. Identification as urban site was based on criteria provided by Urban Development and Housing Department, Government of Sikkim, Gangtok.

The study was conducted during the period of April, 2013 to October, 2015. A total of n=700 subjects were screened during this period. They were the target population of the study.

Data Collection: Data collection was based on personal interviews with the participants. Before interview, the participants were explained about the nature and objective of the study and the nature of questions involved. Confidentiality was ensured and it was also mentioned that they have the freedom of refraining from any response. The respondents were also briefed about the need of their honest answers in order to get correct information. Informed consent was obtained from competent person. The informed consent form was originally made in English language and then was translated to Hindi and Nepali language for a better understanding of the participants. They were given a copy of the signed informed consent. Participants were not given any monetary or other compensation in lieu of participation in the study.

Statistical Analysis: Data was fed in Statistical Package for the Social Sciences (SPSS), version 20, IBM Corp. Before analysis all entries were checked and cleaned by ignoring or putting missing value codes for inconsistent or ambiguous values. Chi-square was run for nonparametric data to show the significant difference, if any. A significance level less than 0.05 ($p < 0.005$) was considered as statistically significant. The obtained results were presented in tables and charts.

Table 1: Analgesic Use greater than equal to 10 doses per month in the past 30 days

Category	Frequency (N)	Percentage (%)
Without prescription-Other than everyday kind of pain	91	72.80
With prescription and Without prescription-Regular pain	34	27.20
Total	**125**	**100**

Table 2: Lifetime analgesic use and use of more than one analgesic in the past 30 days

Category	Frequency (N)	Percentage (%)
Lifetime analgesic used in the past 30 days		
Yes	313	44.70
No	387	55.30
More than one analgesic used in the past 30 days		
Yes	**33**	**36.30**
No	**58**	**63.70**

Table 3: Analgesics frequently misused in the past 30 days

Drugs	Frequency (N)	Percentage(%)
Paracetamol	49	53.80
Ibuprofen	**28**	**30.80**
Aspirin	**08**	**8.80**
Diclofenac	**06**	**6.60**

Table 4: Predictors of Analgesic misuse

Category	Analgesic Misuse (%)	No Misuse (%)	P
Pain in the past 30 days			χ^2 = 23.282,
Yes	42 (46.15)	137 (22.50)	df=1, P<0.001
No	49 (53.85)	472 (77.50)	
			χ^2 = 7.326,
Source of Income	37 (45.68)	304 (59.03)	df=2, P=0.026
Salaried	26 (32.10)	101 (19.61)	
Self-employed	18 (22.23)	110 (21.36)	
Unemployed			χ^2 = 2.945,
			df=2, P=0.229
Age	31 (34.07)	243 (39.90)	
15-25 years	35 (38.46)	245 (40.23)	
26-35 years	25 (27.47)	121 (19.87)	χ^2 = 14.430,
36-40 years			df=2, P=0.001
Smoking in the past 30 days	44 (48.35)	407 (66.83)	χ^2 = 5.031,
None	21 (23.08)	113 (18.56)	df=1, P=0.081
Less than 10 times	26 (28.57)	89 (14.61)	
10 times and more			χ^2 = 140.224,
	45 (49.45)	355 (58.29)	df=2, P<0.001
Alcohol use in the past 30 days	34 (37.36)	211 (34.65)	
No use	12 (13.19)	43 (7.06)	
Less than 3drinks/day/week			$\chi^{2=}$0.655,
More than or equal to 3drinks/day/week	15 (16.48)	89 (14.61)	df=2, P=0.721
	23 (25.27)	458 (75.21)	
BMI	53 (58.24)	62 (10.18)	
Below 18.5			χ^2 = 3.929,
18.5 – 24.9			df=2, P=0.140
Above 25.0	39 (42.86)	279 (45.81)	
	21(23.08)	119 (19.54)	
	31(34.07)	211 (34.65)	
Level of Education			
Illiterate and school dropout			χ^2 = 13.811,
School completed			df=2, P=0.001
Graduate and above			
Marital Status	28 (30.77)	209 (34.32)	
Single	59 (64.84)	391 (64.20)	
Married	04 (0.66)	09 (1.48)	
Others			
Depression	11 (12.09)	43 (7.06)	
Most of the time	31 (34.07)	122 (20.03)	
Some of the time	49 (53.85)	444 (72.91)	
None of the time			

[Table 1], [Table 2] and [Table 3] shows the results regarding the frequency of using analgesics and the commonly misused analgesics. Almost 44.7% of participants were seen to use analgesics over their lifetime, among them 13% were seen to misuse analgesics. Among the analgesics misused, paracetamol (53.8%), ibuprofen (30.8%), aspirin (8.8%) and diclofenac (6.6%) were the commonest. Almost 36.3% of participants misuse more than one analgesic in the past 30 days.[Table 4] show the predictors of analgesic misuse. Statistically significant results were obtained for pain the past 30 days (χ^2 = 23.282, df=1, P<0.001), source of income (χ^2 = 7.326, df=2, P=0.026), smoking in the past 30 days (χ^2 = 14.430, df=2, P=0.001), body mass index (χ^2 = 140.224, df=2, P<0.001) and depression (χ^2 = 13.811, df=2, P=0.001).

Discussion

The study is an effort to understand the misuse of analgesics and predictors of analgesic misuse among the young adult population. [Table 1] shows the analgesics misused among the urban young adults of East Sikkim. In our study, almost around 13% of the participants were seen to misuse analgesics. For such users, the risk of getting addicted is the highest, especially when medicines are not taken under a physician's supervision. [Table 2] and [Table 3] shows the analgesic use in the past 30 days and the commonly misused analgesics. In a research conducted among 295 clients of French pharmacies, it has been stated that the problem of misusing OTC pain relievers may concern 6.8–17% of users. The risk of abuse was higher in the case of paracetamol users. [14] In another study conducted among adults of Wroclaw, Poland, the "heavy users" more regularly bought medicines with ibuprofen – 57%. [15] This was in compliance with the results reported in our study where paracetamol misused by almost 53.8% of the participants, which shows the highest and the next in line was ibuprofen (30.8%). [Table 2] from the Finnish study among participants 15-74 years, frequent analgesic use was related especially to daily or continuous pain and high pain intensity. Low mood, depression and not being employed also increased the probability for daily analgesic use. [16] However, the Wroclaw, Poland study reported that the better-educated, professionally active people expect fast and optimal benefits and had no opportunities to visit their doctors quickly in case of pain. Buying and using analgesics without medical supervision was the best way to relieve pain. [15] In this study, pain in the past 30 days (46.15%) and salaried individuals (45.68%) predicted analgesic misuse. From a study conducted in Denmark, measures of QoL, e.g., poor self-rated health & fitness and increasing age and smoking predicted analgesic use. Other predictors of analgesic use were nulliparity, low level of education, overweight/obesity & binge drinking. Other predictors of analgesic use were underweight and marital/cohabiting status. [17] Smoking in the past 30 days with less than 10 times (23.08%) and more than 10 times (28.57%) also predicted analgesic misuse in this study. Individuals with higher BMI (58.24%) caused an increased misuse of analgesics. Also depressed (46.15%) individuals were seen to misuse the analgesics.

Conclusion

Regular monthly analgesic use greater than or equal to 10 doses was generally prevalent. Regular analgesic use was reported to be without medical advice and for pain other than everyday kind. Several socio-demographic and lifestyle factors along with smoking in the past one month were associated with a continuous regular analgesic misuse.

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