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Original Research Article

PREVALENCE AND CHARACTERISTICS OF ANALGESICS MISUSED AMONG URBAN YOUNG ADULTS OF EAST SIKKIM: A CONTROLLED, CROSS-SECTIONAL STUDY

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Abstract: Prescription medications are being consumed worldwide without any medical supervision, and the improper use of prescription analgesic misuse has emerged as a serious health issue. Several studies have been conducted in different countries to understand the prevalence and characteristics of analgesic misuse.

This study is aimed at estimating the prevalence and characteristics of analgesic misuse in an urban area of Sikkim in a young adult population (15 – 40 years of age) of either sex.

A pre devised questionnaire on the population survey of analgesic misuse and brief pain inventory was administered to n=700 participants after obtaining the informed consent. Data was statistically analyzed using SPSS software.

Prevalence of analgesic misuse was found to be 13%. Mostly tablets (92.30%) were being consumed, without prescription (75.80%) and only one analgesic was being used (63.70%) for almost a year or more. Majority of the participants didn't change analgesics ever (89.0%) and never undergone any treatment for pain (83.50%). Majority of the participants were unaware of the effects of analgesic use (94.50%).

Misuse of analgesics was prevalent. Most of the analgesics misused were in tablet form and were obtained without prescription and self-medication was prevalent and very few participants undergone any treatment for pain.

Key words: Analgesic, Misuse, Prevalence, Characteristics, Sikkim.

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Introduction: Misuse of prescription medications and its medical and social consequences are likely to be an important public health problem. This is more significant in a country like India, where there is little control at the population level over procurement of medications without prescriptions. As per WHO, Drug misuse is defined as the use of a

drug or substance including prescription medications for a purpose not consistent with legal or medical guidelines.[1]

Prescription drug misuse is a global public health problem. Many medications with sedative, anxiolytic, analgesic or stimulant properties have the potential to be inappropriately used without medical supervision. Analgesics are one of the commonest categories of medications routinely used by the general population and are available without prescription and over-the-counter (OTC). Regular medically unsupervised analgesic use has a likelihood of causing significant medical and consequent social harm over time. A number of studies from different countries have investigated this problem in different contexts and in different age groups. There is currently a lack of consensus about what constitutes prescription misuse and a wide range of opinions have been proposed. Inappropriate medication use is frequently defined on the basis of characteristics of users (i.e., any non-prescribed use), the reason for use (i.e., use for recreational purposes), the presence of clinically significant symptoms (i.e., meeting diagnostic criteria for abuse and dependence) or on the presence of any of these factors. In cases where multiple criteria are used to define misuse there is often a lack of differentiation among them and various studies use more specific criteria to exclude or include certain types of misuse from consideration altogether.[2]

In the United States of America (USA) national surveys have shown a significant increase in non-medical use of prescription drugs with a particular increase in use of analgesics. Almost 6.4 million or 2.6% Americans were using prescription-type psychotherapeutic drugs without medical supervision in the past month. Of these, 4.7 million used analgesics and the current non-medical use of prescription-type drugs among young adults aged 18 – 25 increased from 5.4% in 2002 to 6.3% in 2005.[3]

Apart from the USA misuse of analgesics is an important health issue in other countries also. In a study from Australia, analgesic nephropathy or analgesic abuse-associated analgesic nephropathy (AA-AAN) has been recognized as a disease of the twentieth century. It was recorded that the emergence of AA-AAN was due to aggressive marketing of analgesics and the susceptibility of individuals with addictive personalities to analgesic abuse.[4]

Evidence suggests that 'non-prescribed' medication use can involve a wide-range of behaviors and motives that might be associated with very distinct user characteristics and risks. For example, non-prescribed uses of the same medication might include very hazardous uses for intoxicating purposes (e.g. use of high doses intravenously and in combination with alcohol or other drugs) as well as therapeutic use for a bona fide condition outside of a physician's supervision (e.g. taking a single therapeutic oral dose of a friend or relative's medication to treat symptoms for which the prescription is normally indicated). While each of these forms of misuse may be of clinical interest, they likely pose very different risks and have very different associated features.[5]

Sikkim is a hilly state in North East India and is located in the foothills of the Himalayas. Sikkim shares international borders with Nepal, Bhutan and Tibet and it has observed great changes in its social & political structure, economic life and cultural values during the past few decades.[6]

Although systematic data on prescription drug misuse is not available in India one study has demonstrated a high consumption of prescription medications among children with significant consumption of analgesics. One hundred and seventy two children were prescribed, in 212 episodes of illness, antimicrobial agents (28.4%), followed by anti-diarrheals (10.9%), nutritional products (9.4%), analgesics (7.5%) and steroids (6.8%).[7] Thus, a number of studies have been conducted in other countries to estimate the problem of analgesic misuse, however very little information is available from the Indian scenario. Therefore,

the present study has an important public health implication.

This study was conducted to understand the prevalence and factors causing misuse of analgesics in an urban area of Sikkim in a young adult population (15 – 40 years of age) of either sex. 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.[2, 8, 9, 10]

Materials and Methods

Selection of study subjects: Youth is defined as men and women in the age group of 15 – 24 years;[11] and young adults are considered up to the age of 40 years.[12] In this study only young adults (15 – 40 years of age) of either sex was 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 prevention measures.

Sampling Method & Size: Current population of Gangtok is approximately 98,568,[13] 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.[14] 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 – 25 years, 26 – 35 years and 36 – 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.

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.[15]

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 a period of 2013 to 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. During interview local Nepali language, Hindi or English was used as per the convenience of the participant. Questionnaires on analgesic misuse, brief pain inventory were recorded on the printed paper questionnaire form from each of the study participants. Participants were not given any monetary or other compensation in lieu of participation in the study.

Statistics: 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. Frequency distribution and percentage for characteristics of analgesics misused was estimated.

Results: [Table 1] shows the characteristics of analgesic misused among urban young adults. Most of the participants were found to be using mostly one analgesic in past month (63.7%) in tablet form (92.3%) for less than 10 days (53.80%) a month. Frequency of 10 doses of analgesics used for 1 year or more (50.5%) without prescription (75.8%) was observed. Use of analgesics of less than or equal to 15 doses/month (74.7%) was observed with analgesics not ever being changed (89%). With most of the participants who had undergone treatment (16.5%), only 15.38% had been satisfied with pain treatment. Self-medication was observed in 6.60% as participants not satisfied with pain treatment with 94.50% participants who were unaware of the effects of analgesic misuse and also reported the easy availability of analgesics (97.8%).

[Table 2] shows the prevalence of analgesic misuse. According to our study, 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. The prevalence of analgesic misuse was calculated by measuring the presence of analgesic misuse in a sample of the population selected randomly, then dividing the number of participants with analgesic misuse by the number of participants in whom it was measured. Prevalence is often expressed as a percentage. Prevalence as measured equals to 13% in our study.

Table 1: Characteristics of Analgesics misused among urban young adults

Variables	Category	N	Percentages
Dosage of Analgesic	Tablet	84	92.30
	Others	07	7.70
Frequency of Analgesic use	Less than 10 days	49	53.80
	10 to 30 days	42	46.20
More than one analgesic used in past month	Yes	33	36.30
	No	58	63.70
Frequency of 10 doses of analgesic used	6 months	16	17.60
	6 months to less than 1 year	29	31.90
	1 year or more	46	50.50
Frequency of doses of analgesics	10-15 doses/month	68	74.70
	16-30 doses/month	21	23.10
	>30 doses/month	2	2.20
Sources of analgesic use	Without prescription	69	75.80
	Both	22	24.20
Have you ever changed analgesics?	Yes	10	11.00
	No	81	89.00
Satisfied in getting pain relief	Yes	76	83.50
	No	15	16.50
Treatment of pain ever taken?	Yes	15	16.50
	No	76	83.50
Have you even been satisfied with pain treatment?	Yes	14	15.38
	No	01	1.10
	Not Applicable	76	83.52
Does respondent self-medicate because not satisfied with pain treatment?	Yes	06	6.60
	No	85	93.40
Are you aware of effects of analgesic use?	Yes	05	5.50
	No	86	94.50
Ease of analgesic availability	Yes	89	97.8
	No	02	2.2

Table 2. Prevalence of Analgesic Misuse

$$\frac{\text{Number of participants with Analgesic misuse} \times 100}{\text{Number of total participants measured}} = \text{Prevalence (as \%)}$$

$$\frac{91}{700} \times 100 = \text{Prevalence (as \%)} = 13\%$$

Discussion: The study is an effort to understand the prevalence and characteristics of analgesics misused among the young adult population. [Table 1] shows the characteristics of analgesics misused among urban young adults. Mostly tablets (92.30%) were being consumed, without prescription (75.80%) and only one analgesic was being used (63.70%) for almost a year or more. Majority of the participants didn't change analgesics ever (89.0%) and never undergone any treatment for pain (83.50%). In a study, self medication for pain was carried out to understand the attitudes about self-medication for pain relief and features of self-medication in first-year students of the University of Applied Health Studies in Zagreb, Croatia.[16] In this study, self-medication (93.40%) was being carried out and majority of the participants were unaware of the effects of analgesic use (94.50%). In a study conducted in Bangalore, chemist shops were found to be the main source of obtaining prescription drugs non-medically.[17] Another study conducted in Brazil where 70 pharmacies located in Sao Paulo were randomly selected and visited to investigate over-the-counter availability of analgesics. 7 researchers posed as ordinary clients presenting with a standardized complaint of symptoms, asked for medicines to relieve his / her pain or discomfort. After the seller's suggestion the client asked for two drugs randomly selected from a drug list containing 30 trademarked drugs commonly prescribed to arthritis patients. These drugs should be available only on prescription. In only 12.8% of the pharmacies did the seller initially suggest the client to consult a physician. The sellers "prescribed" non-steroidal anti-inflammatory drugs (NSAID), vitamins, analgesics (AN) and corticosteroids (CO) in respectively 42.8, 20.0, 14.3 and 5.7% of the visits. From the drug list, the client could secure 67.7% of the NSAIDs, 65.0% of the CO and 20.0% of the sedatives without presenting a prescription. In our study also participants also mentioned about the easy availability of analgesics (97.8%). [Table 2] shows the prevalence of analgesic misuse among the young adult population. Prevalence of analgesic misuse in our study was reported to be 13%. In a Finnish study among participants 15 – 74 years (n=6,500), after adjusting for age and sex, the overall prevalence of daily analgesic use was 8.5% & prevalence of analgesic use a few times a week 13.6%.[18] In a study from Denmark among participants in the age group 18 – 45 years (n=45,000), 27% women & 18% men reported regular monthly use of at least seven analgesic tablets during the last year.[19] Studies in Switzerland among endurance athletes in mass sport examining the use of medications before an event showed a prevalence between 5 and 10% of NSAID misuse. [20] In a study from China, the prevalence of current use of Non Steroidal Anti-Inflammatory Drugs was 9.6% without prescription. [9] Although systematic data on prescription drug misuse is not available in India one study has demonstrated a high consumption of prescription medications among children with significant consumption of analgesics. One hundred and seventy two children had consumed, in 212 episodes of illness, antimicrobial agents (28.4%), followed by anti-diarrheals (10.9%), nutritional products (9.4%), analgesics (7.5%) and steroids (6.8%).[7] Prevalence of regular analgesic misuse is in the range of 7.2% – 35% as seen from European studies.[18, 19] Therefore, prevalence of analgesic misuse as reported from this study and other European studies across different countries falls in place when compared.

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. Most of the analgesics misused were in tablet form and were obtained without prescription and self-medication was prevalent and very few participants undergone any treatment for pain.

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