Health Related Quality of Life of Urban Young Adults Misusing Analgesics Participating in a Controlled, Cross-sectional Study in East Sikkim, North East India

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ABSTRACT

Pharmacology Section

Introduction: A great deal of interest exists in assessing the health related Quality of Life (QoL) as an important aspect of treatment effectiveness with prescription drug misuse. The SF-36 Health Survey is a self-report measure assessing subjective health status along with physical and mental health domains.

Aim: To evaluate how analgesic misuse affects both physical and emotional QoL in an urban area of Sikkim in a young adult population (15-40 years of age) of either sex.

Materials and Methods: This study was a cross-sectional general population survey. Proposed study site included an urban area in East Sikkim. A pre-devised questionnaire of SF-36 was administered to 700 subjects. Data were statistically analysed using Statistical Package for Social Sciences software version 20.0.

Results: Significant difference among analgesic misusers and non misusers in measures like general health (χ^2 =17.197, df=2, p<0.001), compared to one year ago, health condition now (χ^2 =8.379, df=2, p=0.015), emotional health-depression (χ^2 =13.811, df=2, p=0.001), emotional health-full of life (χ^2 =8.998, df=2, p=0.011), emotional health-felt dumped (χ^2 =6.065, df=2, p=0.048), emotional health-energy (χ^2 =13.190, df=2, p=0.001), emotional health-worn out (χ^2 =6.325, df=2, p=0.042) was found.

Conclusion: This study could identify a subset of participants in their youth with current pain and several measures of low QoL in emotional domain like depression, full of life, energy; felt dumped, worn out in the past four weeks in subjects misusing analgesics. Low QoL also identifies possibility of future onset of mental and psychiatric impairments.

Keywords: Abuse, Addiction, Drug, Pain, Prescription

INTRODUCTION

In the medical field, assessing QoL is more than a simple description of a patient's health; rather, QoL is seen as how patients perceive and react to their health status as well as to other non medical areas of their lives [1]. Since, the early 1980s, there has been an explosion of studies and reviews that have focused on QoL issues in the healthcare field. However, relatively little has been done in the field of prescription drug misuse to integrate health-related QoL into the assessment of outcomes [2,3].

In a country like India, where there is little control at the population level over the procurement of medications without prescriptions, misuse of prescription medications is an important public health issue. 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 [4].

Medically unsupervised use of analgesics has a likelihood of causing significant medical and consequent social harm over a period of time. A number of studies from different countries have investigated this problem in different contexts and in different age groups. Non medical use of prescription type drugs has increased in the USA. Use of these psychotherapeutic drugs without proper care and direction were seen in almost 6.4 million (2.6%) Americans. Out of 6.4 million, 4.7 million American young adults used analgesics who were in the age group of 18-25 years, which increased from 5.4% in 2002 to 6.3% in 2005 [5]. Chronic back pain was reported among the participants in the age group of 10-19 years of age and chronic idiopathic pain among the adolescents as per several studies conducted [6]. Studies show presence of chronic pain which may predispose to alcohol and other illicit drug use in youth and comorbid depression is a risk factor of suicide ideation and attempt among adolescents [7,8].

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Sikkim, a hilly state in North East India has observed great changes in its social and political structure, economic life and cultural values during the past few decades [9]. As a result, lot of migration took place from different states of India, resulting in the introduction of new and different perceptions of individuals towards health-related QoL and its assessment of outcomes.

The objective of this study was to identify how analgesic misuse affects physical and emotional QoL, as poorer QoL in both domains may predict future onset of medical and psychiatric morbidities.

MATERIALS AND METHODS

A cross-sectional, general population survey was conducted from March 2013 to September 2015 among urban young adults of East Sikkim in the age group of 15-40 years.

Study site included an urban area in East Sikkim. The selected urban site was Gangtok, East Sikkim, the most important city in Sikkim. Identification of Gangtok as urban site was based on criteria provided by Urban Development and Housing Department (UDHD), Government of Sikkim, Gangtok.

Men and women in the age group of 15-24 years are defined as youth and young adults are considered up to the age of 40 years [10,11]. In this study only young adults (15-40 years of age; below and above this age group were excluded) of either sex were recruited as participants since these group presents with comorbid agerelated chronic medical conditions that might lead to more use of analgesics, also they have a tendency to develop adverse outcomes of regular use of analgesics as well as might cause dependence over a period of time.

Sampling method and size: The population of Gangtok, when the study was designed, was 98,658, i.e., approximately 1,00,000

[12]. According to the population pyramid of India approximately 35% of the total population belongs to the age group of 15-40 years [13]. Hence, an approximate 35,000 people are expected to be in the age group of 15-40 years. Prevalence of regular analgesic use as reported from several European studies in age groups above 14 years has been reported in the range of 7.2-34.8%. In this study, for a younger age group of the study population (15-40 years) an estimated prevalence of 5% analgesic misuse with an acceptable lower limit of 2% were assumed. To detect the prevalence at a 95% Confidence Interval (CI), the study enrolled n=700 participants from Gangtok site. During recruitment for the study, stratification according to age groups and gender was carried out and was adjusted according to actual percentage of population of the same.

Sampling locations in each site were identified. Mostly schools were included where people in the age group of 15-17 years aggregate, colleges (18-22 years) and households where participants in the age group of 15-40 years were easily available. This study surmises more as an ethnographic one with strict inclusion criteria of age group, i.e., 15-40 years of either sex.

The case record form constituted the following:

A generic 21 item questionnaire on sociodemographics based on the age, gender, education, ethnicity, religion, marital status. It also focused on questions that deals with alcohol use and smoking.

A generic 21 item analgesic misuse questionnaire, which measured the use of Nonsteroidal Anti-inflammatory Drugs (NSAIDs) and opioid analgesics without prescription [14].

SF-36 is a 11-item QoL questionnaire, which assessed the QoL in different domains. It is a highly reliable (Cronbach's alpha greater than 0.85, reliability coefficient greater than 0.75 for all dimensions except social functioning) and valid instrument in terms of distinguishing between the groups with significant health differences [15].

Ethical issues: The study protocol, instruments/questionnaire, informed consent was duly approved by Institutional Ethics Committee (IEC).

Data Collection

During data collection, the participants were well explained about the nature and objective of the study before beginning with the face to face interviews. Responses of the questionnaires were coded by numbers and at no time participant's name/photo were associated with participant's responses to the questionnaire (to encourage an honest approach to the questions asked) so that full confidentiality was maintained. Participation for this study was voluntary. At any time participant had complete freedom to withdraw from the study, if desired so.

Informed consent was obtained. The informed consent form used for data collection was made in three different languages of English, Hindi and Nepali.

They were given a copy of the signed informed consent. During interview local language (Nepali), Hindi or English was used as per the convenience of the participant. Questionnaire on QoL aspects and analgesic misuse 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. Data were de-identified, coded, entered and encrypted in secure files.

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, premenstrual syndrome) without medical advice [16-18]. Body Mass Index (BMI) was calculated and expressed in kilogram/square meter. SF-36 questionnaire was collated for an easy statistical use [6].

STATISTICAL ANALYSIS

Data were fed in Statistical Package for the Social Sciences (SPSS), version 20.0, IBM Corp. All the data fed in the software were checked for incorrect or any missing values before beginning the analysis. Frequency distribution was used to describe nature, extent and patterns of analgesic use. Chi-square was run for non parametric data to show the significant difference, if any.

RESULTS

The [Table/Fig-1] shows QoL among urban young adults in the study. For parameters like general health and health now compared to one year ago showed maximum percentage for good to excellent health and about the same as one year ago. And, also maximum percentage was observed for variables: not limited at all and minimum for: limited a lot.

Variables	Category	Frequency	Percentages
General health condition	Excellent to good	263	37.6
	Fair	188	26.9
	Poor	249	35.5
Health condition now, compared to one year ago	Better	59	8.4
	About the same	490	70.0
	Worse	151	21.6
Moderate activities, limited by health condition	Yes, limited a lot	155	22.1
	Yes, limited a little	271	38.8
	No, not limited at all	274	39.1
Lifting or carrying groceries, limited by health condition	Yes, limited a lot	78	11.1
	Yes, limited a little	121	17.3
	No, not limited at all	501	71.6
Climbing several flights of stairs, limited by health condition	Yes, limited a lot	96	13.7
	Yes, limited a little	246	35.1
	No, not limited at all	358	51.1
(Table / Fig. 1): Quality of life (backth status) among urban young adults (n - 700)			

The [Table/Fig-2] shows QoL (problems faced due to physical and emotional problems) among the study participants. For most of the parameters, maximum percentage was observed for: none of the time at more than 60% and minimum for: most of the time at less than 15% and a medium range for: some of the time at 14-25%.

Variables	Category	Frequency	Percentage
Cut down amount of time spent on work/activity, due to physical	Most of the time	72	10.3
	Some of the time	181	25.9
health, past four weeks	None of the time	447	63.9
	Most of the time	69	9.9
Accomplish less work, due to	Some of the time	158	22.6
	None of the time	473	67.6
Limited in the kind of work or	Most of the time	39	5.6
other activities, due to physical health, past four weeks	Some of the time	145	20.7
	None of the time	516	73.7
Cut down on the amount of time spent on work, due to emotional	Most of the time	94	13.4
	Some of the time	129	18.4
problem, past four weeks	None of the time 447 66 Most of the time 69 9 Some of the time 158 2 None of the time 158 2 None of the time 473 66 K or sical Most of the time 39 5 Some of the time 145 22 None of the time 145 22 None of the time 516 7 time Most of the time 94 1 Some of the time 129 1 None of the time 477 6 Most of the time 70 1 Some of the time 104 1 None of the time 526 7 I or Not at all 464 6 Moderately 166 2 1	68.1	
Accomplish less work due to	Most of the time	70	10.0
emotional problem, past four	Some of the time	104	14.9
weeks	None of the time	526	75.1
Extent of physical health or emotional problem interfered with your normal social activity	Not at all	464	66.3
	Moderately	166	23.7
past four weeks	Quite a bit	70	10.0
[Table/Fig-2]: Quality of life (pr	roblems faced due	to physical a	and emotional

The [Table/Fig-3] shows comparison of QoL among participants having pain and no pain in the past four weeks statistical significant differences were observed like compared to one year ago, health condition now, moderate activities, emotional health-depression, emotional health-happy, emotional health-full of life, emotional health-worn out.

Measures of QoL	Subjects having pain n=179 (%)	Subjects having no pain n=521 (%)	p-value
General health			
Good to excellent	55 (30.7)	208 (39.9)	χ²=4.810, df=2,
Fair	53 (29.6)	135 (25.9	
Poor	71 (39.7)	178 (34.2)	p=0.090
Compared to one	year ago, health conditi	on now	
Better	11 (6.1)	48 (9.2)	_
About the same as 1 year ago	115 (64.2)	375 (72.0)	χ ² =9.828, df=2, p=0.007
Worse	53 (29.6)	98 (18.8)	
Moderate activitie	s		
Limited a lot	43 (24.0)	112 (21.5)	γ ² =10.832.
Limited a little	84 (46.9)	187 (35.9)	df=2,
Not limited at al	52 (29.1)	222 (42.6)	p=0.004
Physical health, cu	ut down amount of time	spent on work	
Most of the time	23 (12.8)	49 (9.4)	γ ² =0.390,
Some of the time	47 (26.3)	134 (25.7)	df=2,
None of the time	109 (60.9)	338 (64.9)	p=1.882
Accomplish less v	vork, due to physical he	alth	
Most of the time	22 (12.3)	47 (9.0)	$\gamma^2 = 0.166.$
Some of the time	46 (25.7)	112 (21.5)	df=2,
None of the time	111 (62.0)	362 (69.5)	p=3.587
Emotional health,	cut down amount of tim	e spent on work	
Most of the time	29 (16.2)	65 (12.5)	χ ² =2.390,
Some of the time	28 (15.6)	101 (19.4)	df=2,
None of the time	122 (68.2)	355 (68.1)	p=0.303
Accomplish less v	vork, due to emotional p	roblem	
Most of the time	22 (12.3)	48 (9.2)	$\gamma^2 = 4.437.$
Some of the time	33 (18.4)	71 (13.6)	df=2,
None of the time	124 (69.3)	402 (77.2)	p=0.109
Emotional health-	depression		
Most of the time	22 (12.3)	32 (6.1)	$v^2 = 8.597$
Some of the time	43 (24.0)	110 (21.1)	df=2,
None of the time	114 (63.7)	379 (72.7)	p=0.014
Emotional health-	happy		
Most of the time	48 (26.8)	181 (34.7)	w ² 6 405
Some of the time	58 (32.4)	178 (34.2)	χ ² =6.405, df=2, p=0.041
None of the time	73 (40.8)	162 (31.1)	
Emotional health-	nervous		
Most of the time	14 (7.8)	39 (7.5)	2 0 0 40
Some of the time	38 (21.2)	114 (21.9)	χ²=0.048, df=2,
None of the time	127 (70.9)	368 (70.6)	p=0.976
Emotional health-	full of life		
Most of the time	27 (15.1)	88 (16.9)	
Some of the time	88 (49 2)	312 (59 9)	χ ² =10.859, df=2
None of the time	64 (35.8)	121 (23.2)	p=0.004
Emotional health-	felt dumped	121 (20.2)	
Most of the time	10 /7 0	20 (2 S)	
Some of the time	10 (7.0)	100 (00 0)	χ ² =3.863,
None of the time	126 (70 4)	302 (75 2)	p=0.145
	120 (10.4)	032 (10.2)	

[Table/Fig-4] shows comparison of QoL among participants misusing analgesics and not misusing analgesics. There was significant difference among analgesic misusers and non misusers in measures like general health, compared to one year ago, health condition now, emotional health-depression, emotional health-full of life, emotional health-felt dumped, emotional health-energy, emotional health-worn out.

Measures of QoL	Analgesic misus- ers n=91 (%)	Analgesic non- misusers n=609 (%)	p-value
General health			
Good to excellent	23 (25.3)	240 (39.4)	χ²=17.197, df=2,
Fair	18 (19.8)	170 (27.9)	
Poor	50 (54.9)	199 (32.7)	p<0.001
Compared to one year ago, he	alth condition now		
Better	08 (8.8)	51 (8.4)	γ²=8.379,
About the same as one year ago	53 (58.2)	437 (71.8)	χ =0.379, df=2,
Worse	30 (33.0)	121 (19.9)	p=0.015
Moderate activities			
Limited a lot	24 (26.4)	131 (21.5)	$\chi^2 = 1.967$
Limited a little	37 (40.7)	234 (38.4)	df=2,
Not limited at all	30 (33.0)	244 (40)	p=0.374
Physical health, cut down amo	ount of time spent or	n work	
Most of the time	12 (13.2)	60 (9.9)	w ² -1.000
Some of the time	19 (20.9)	162 (26.6)	χ²=1.929, df=2, p=0.381
None of the time	60 (65.9)	387 (63.5)	
Accomplish less work, due to	physical health		
Most of the time	13 (14.3)	56 (9.2)	w ² -0 205
Some of the time	20 (22.0)	138 (22.7)	χ²=2.325, df=2, p=0.313
None of the time	58 (63.7)	415 (68.1)	
Emotional health, cut down an	nount of time spent	on work	
Most of the time	11 (12.1)	83 (13.6)	$\gamma^2 = 0.922$
Some of the time	17 (18.7)	112 (18.4)	df=2,
None of the time	63 (69.2)	414 (68.0)	p=0.162
Accomplish less work, due to	emotional problem		
Most of the time	06 (6.6)	64 (10.5)	χ²=5.053,
Some of the time	08 (8.8)	96 (15.8)	df=2, p=0.080
None of the time	77 (84.6)	449 (73.7)	
Emotional health-depression			
Most of the time	11 (12.1)	43 (7.1)	χ ² =13.811, df=2, p=0.001
Some of the time	31 (34.1)	122 (20.0)	
None of the time	49 (53.8)	444 (72.9)	
Emotional health-happy			
Most of the time	28 (30.8)	201 (33.0)	v ² -0.834
Some of the time	30 (33.0)	206 (33.8)	χ =0.034, df=2, n=0.364
None of the time	33 (36.3)	202 (33.2)	p=0.364

Emotional health-nervous			
Most of the time	8 (8.8)	45 (7.4)	χ ² =3.434, df=2, p=0.180
Some of the time	13 (14.3)	139 (22.8)	
None of the time	70 (76.9)	425 (69.8)	
Emotional health-full of life			
Most of the time	16 (17.6)	99 (16.3)	χ ² =8.998, df=2, p=0.011
Some of the time	40 (44.0)	360 (59.1)	
None of the time	35 (38.5)	150 (24.6)	
Emotional health-felt dump	ed		
Most of the time	07 (7.7)	26 (4.3)	χ ² =6.065, df=2, p=0.048
Some of the time	26 (28.6)	123 (20.2)	
None of the time	58 (63.7)	460 (75.5)	
Emotional health-energy			
Most of the time	39 (42.9)	208 (34.2)	χ²=13.190, df=2,p=0.001
Some of the time	26 (28.6)	293 (48.1)	
None of the time	26 (28.6)	108 (17.7)	
Emotional health-worn out			
Most of the time	10 (11.0)	28 (4.6)	χ ² =6.325, df=2, p=0.042
Some of the time	24 (26.4)	167 (27.4)	
	E7 (60 6)	414 (69.0)	

DISCUSSION

The present investigation explored predictors of low QoL in the young adult population of East Sikkim. Almost 25.57% of the population reported some pain which coincides with the observation of chronic pain reported in a relatively younger population [19,20].

As observed from the QoL (problems faced due to physical and emotional problems) among urban young adults, for most of the parameters, maximum percentage was observed for: none of the time at more than 60% and minimum for: most of the time at less than 15% and a medium range for: some of the time at 14-25%.

This study measured QoL in three main domains; general, physical and emotional. General health was found to be statistically significant in analgesic misusers. General health and compared to one year ago, health condition now and moderate activities carried out in the past four weeks were also found to be statistically significant in subjects having pain. Special emphasis was given to the emotional domain as low QoL in this domain predicted by chronic pain may increase the risk of future onset of substance use disorder and other psychiatric disorders in later life. The study identified few important measures of low emotional QoL with statistical significance in subjects having pain; depression in the past four weeks, happiness in the past four weeks, full of life in the past four weeks and worn out in the past four weeks. In misusers of analgesics, important measures of low emotional QoL with statistical significance were depression in the past four weeks, full of life in the past four weeks, felt dumped in the past four weeks, energy in the past four weeks and worn out in the past four weeks. There are higher levels of ill-health and physical impairment among substance misusers than in the general population as reported by Grant B and Pickering M [21]. Another study where patients from a managed care organisation who filled > or =1 NSAID use over a six month period were reported to have an easy accessibility of Over-the Count (OTC) medications, which may contribute to patients using more than one NSAID to manage pain. From the study it was reported the use of NSAIDs was associated with lower scores indicating poorer health related QOL [22].

LIMITATION

Little background information was available on the prevalence of the prescription misuse problem in India, which was a limitation in designing the study. Also, this study was conducted only in one urban site in East Sikkim, i.e., Gangtok and therefore a limitation in generalisation of findings. We had restricted the age of the participants to 15-40 years and did not include participants in age groups below and above, which again limits the scope of present study. Ethnic disparity of enrolling more number of Nepalis in the study could have been decreased by enrolling more participants from other ethnic groups depending on the presence of the problem.

CONCLUSION

This study could identify a subset of participants in their youth with current pain and several measures of QoL in emotional domain like depression, full of life, energy etc; in the past four weeks in subjects misusing analgesics. Low QoL in more than one emotional domain also identifies possibility of future onset of mental and psychiatric impairments.

Since, this study provides an idea about the possible factors resulting in analgesic misuse, this shall provide baseline information to design further studies in the future and to detect risk factors of analgesic misuse and its impact on the QoL. Future studies shall aim to help formulate prevention measures and is expected to have a policy impact.

Moreover, studies can be conducted on a broader aspect in both the urban and rural different areas of Sikkim as well as in different parts of our country to understand the prevalence and the predictors causing analgesic misuse.

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