

# Prevalence and Determinants of Over-the-Counter Analgesics Usage among Patients attending Primary Health Care Centers in Jeddah, Saudi Arabia

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## ABSTRACT

**Objective:** To estimate the prevalence and describe the pattern of OTC use among patients attending primary healthcare (PHC) centers, and to assess their knowledge and attitude regarding the related side effects.

**Method:** A cross-sectional study was carried out among 400 adult patients attending the General Medicine clinic in 10 selected PHC centers in Jeddah, Saudi Arabia. The data collected included socioeconomic parameters, practice and pattern of OTC analgesics use in past 6 months, knowledge and attitude about OTC analgesics, and safety assessment. **Results:** Results showed that 84.4% of the participants were using OTC analgesics, at least twice per week in 59.3% of the cases, and for <1 week duration in 65.8%. The prevalence of use was highest among illiterate and highly educated participants ( $p=0.000$ ), and those with moderate income ( $p=0.011$ ). Acetaminophen (paracetamol) was the most frequently used drug (86.1%), followed by ibuprofen (25.1%) and diclofenac (14.7%); and headache (71.1%), arthralgia (17.7%) and toothache (17.4%) were the most common conditions leading to usage. A simple health problem (64.0%), previous experience with the drug (35.1%) and lack of time (12.1%) were the most common reasons for OTC analgesics use. Among all, 58.1% admitted having no knowledge about OTC analgesic side effects; while 7.1% reported having experienced side effects. **Conclusion:** There is an alarming prevalence of OTC analgesics use among patients, with inadequate

levels of awareness about the associated risks. Awareness and knowledge of users should be further investigated to determine the need for information for this specific or a larger population.

**Key words:** Analgesics, Auto medication, Non-steroid anti-inflammatory, Over-the-counter, Painkiller, Paracetamol.

## Key Message

There is high prevalence of OTC analgesics usage combined with low levels of awareness and knowledge about the related hazards; which exposes to misuse that may carry accidents and severe side effects especially among the high-risk populations. The lack of awareness and knowledge highlights the need for targeted information.

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## INTRODUCTION

Analgesics, including non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol (acetaminophen), are the most commonly used over-the-counter (OTC) drugs in the world.<sup>1,2</sup> Over-the-counter analgesics represent a convenient solution for self-care and are generally safe, if used in appropriate dosage. It is important to understand the determinants of the consumption of OTC analgesics, especially in high-risk population such as the elderly and individuals with comorbid conditions, as they are more vulnerable to eventual adverse events.<sup>3,4,5,6</sup> Further, long-term consumption of OTC analgesics may result in severe adverse events, such as a loss of cognition, dehydration, depression, incontinence, poor quality of life and hospitalization.<sup>7</sup> Approximately 25% of the patients taking NSAIDs face several adverse events, even in case of prescribed drug; and several cases of deaths are reported in relation with acetaminophen overdoses.<sup>8,9</sup> On the other hand, OTC analgesics are generally perceived as non-harmful by the population; and consequently, many users end up with misuse.

In the developed countries, sale, purchase and consumption of OTC analgesics are strictly regulated since 1998. However, there is still a need to develop a comprehensive strategy to educate people and make effective legislations to prevent the misuse of OTC analgesics and the associated risks.<sup>10</sup> It is important to increase awareness and knowledge about OTC

analgesics usage and their possible side effects and to screen and prevent risky behaviors and attitudes among users. In Saudi Arabia, several studies investigated the usage of OTC analgesics, either directly or indirectly by exploring self-medication or OTC drugs used in general. A range of objectives has been explored including perception, practice and patterns of usage; but data are still scarce to estimate the need for information among the local population. Thus, such studies are useful to highlight the extent of the risks related to OTC drug use among the population and clarify the role of physicians to educate patients about the potential side effects of OTC analgesics and to keep an adequate level of medical vigilance. In addition, conducting such studies may unveil the gaps in health legislations related to dispensation of OTC analgesics.

The present study aims to provide an insight into the extent of OTC analgesics use and to improve awareness and knowledge about the related health risks among patients visiting primary healthcare (PHC) centers in the Western Province of Saudi Arabia.

## MATERIALS AND METHODS

A cross-sectional study conducted between 1-30 of March 2016, at selected PHC centers in Jeddah, Saudi Arabia. This study involved adult patients (age>15 years) of both genders visiting the General Medicine clinic in

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the participating centers during the study period; while patients visiting other clinics or mentally disabled patients were excluded. The target sample size was calculated to detect an expected 55.4% prevalence of OTC analgesics use,<sup>11</sup> with 5% margin error and 80% statistical power, among a total population of 70,994 in Jeddah PHCs (source: Public Health Administration). Calculated sample size was N=380; which was increased to 400 to compensate for probable dropouts.

Jeddah is divided into 5 supervisory areas including Northern, Western, Eastern, Southern and Centre; each having distinct socioeconomic characteristics and is covered by 6-10 PHCs. A multi-stage stratified sampling technique was used to include eligible participants. In Stage 1, 2 PHC centers were selected from each supervisory area (stratum) using simple random sampling, which gave a total 10 PHC selected centers. In Stage 2, a systematic random sampling (every third patient) was used to include 40 eligible participants from each of the selected PHCs.

A semi-structured questionnaire was translated in Arabic language and administered by the researcher during a face-to-face interview. Face and content validity of the translated version (Arabic) was reviewed by two Family Medicine consultants. The questionnaire was divided into 4 parts as follows: Part 1: sociodemographic and economic data such as age, marital status, educational level, etc.; Part 2: practice and pattern of OTC analgesics use including usage during the past 6 months, frequency and duration of the use, type of drug used (paracetamol, NSAIDs [diclofenac, ibuprofen], or other), health condition leading to usage such as headache, fever, joint pain, etc., pain intensity urging to use (VAS pain score: 0 to 10), supply source such as pharmacy, home stock, supermarket, etc., and reasons for use OTC instead of prescribed analgesics such as minor health problem, lack of time or transport, etc; Part 3: knowledge and attitude about OTC analgesics, including knowledge source (family, pharmacist, media, etc.), practice in reading treatment leaflets, awareness about side effects related to OTC analgesics use, misuse and overdose (hepatotoxicity, nephrotoxicity, gastrointestinal disorders, etc.), and practice in case of inefficacy of the OTC analgesics in reducing pain (visit doctor, stop taking the treatment, continue treatment, etc.); Part 4: safety related to OTC analgesics use including history and type of side effects experienced (nausea and vomiting, stomach ache, rash, etc.), practice in case of side effects (consult doctor, reduce treatment dose, shift to another drug, etc.). The questionnaire was filled by the participants under investigator's supervision.

A pilot study was carried out on a sample of 10% of the total sample size (N=40) to assess validity, clarity and feasibility of the questionnaire. Participants included in the pilot study were excluded from the study.

Both the study protocol and questionnaire were approved by the joint program of family and community medicine and public health administration, represented by the Department of Medical Research and Studies, Directorate of Health Affairs, Jeddah, Ministry of Health. Confidentiality was assured by anonymous data collection and coding of collected data in the database. Verbal consent was obtained from all the participants.

#### Statistical Analysis

Statistical analysis was carried out using SPSS, version 21 (IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp. 2012). Descriptive statistics were used to analyze participants' sociodemographic characteristics, calculate the prevalence and 95% confidence interval (CI) of OTC analgesics use, and describe the patterns of use. Continuous data were presented as mean± standard deviation (SD) and categorical data as frequency (percentages). Factors associated with OTC analgesics use were analyzed by comparing users with nonusers using chi-square test for categorical variables and independent *t*-test for continuous variables. Pattern of OTC use as well as knowledge and attitude were compared

by gender, educational level and family income using chi-square test. A *p*-value<0.05 was considered for statistical significance.

## RESULTS

### Sociodemographic Characteristics of the Study Population

A total of 400 patients attending PHC centers were included (50.3% were females; mean±SD age=35.23±11.14 years). Majority of the participants were married (76.8%), living in Jeddah (96.5%) and having low (42.0%) or very low (20.0%) family income. Professional status indicated a relatively high proportion of unemployed (45.5%) participants, whereas 39.4% were highly educated (university+) (Table 1).

### Prevalence and the Pattern of OTC Analgesics Use

The prevalence (95%CI) of OTC analgesics use was 84.8% (80.8%; 88.1%). The most frequently used drug was acetaminophen (86.1%), followed by ibuprofen (25.1%) and diclofenac (14.7%). Majority of users (67.6%) declared to purchase OTC analgesics at the pharmacy, 45.1% admitted having a personal stock at home, and 4.1% purchased it from the supermarket. Regarding the frequency of use, 59.3% took OTC analgesics at least twice during the past 6 months, for less than a week duration in 65.8% of the cases (Table 2). The most frequent health condition motivating the use of OTC analgesic was headache (71.1%), followed by arthralgia (17.7%) and toothache (17.4%) (Figure 1). Of all

**Table 1 (original): Population characteristics**

Parameter	Category	Frequency	Percentage
Gender	Male	199	49.8
	Female	201	50.3
Age (years)	Mean, SD; [range = 16; 64]	35.23	11.14
Nationality	Saudi	267	66.8
	Non-Saudi	132	33.0
Marital Status	Married	307	76.8
	Single	79	19.8
	Divorced	8	2.0
	Widowed	6	1.5
Educational Level	Illiterate	15	3.8
	Writes and reads	17	4.3
	Primary	31	7.8
	Middle school	38	9.5
	Secondary	136	34.0
	Diploma	23	5.8
	University degree	129	32.3
Residency	Jeddah	386	96.5
	Outside Jeddah	9	2.3
Career	Unemployed	182	45.5
	Retired	17	4.3
	Student	37	9.3
	Employed	159	39.8
Family income (SAR)	Up to 3K	80	20.0
	>3K - 5K	168	42.0
	>5K - 10K	106	26.5
	>10K	41	10.3

Table 2 (Original): Pattern of over-the-counter analgesics usage			
Parameter	Category	Frequency	Percentage
OTC Analgesics use	Yes	339	84.8
	No	61	15.3
Treatment used	Paracetamol	292	86.1
	Ibuprofen	85	25.1
	Diclofenac	50	14.7
	Solpadeine (paracetamol + codeine + caffeine)	8	2.4
	Other	4	1.2
	Panadol extra (Paracetamol + caffeine)	1	0.3
	Lyrica	1	0.3
	Buscopan (Butylscopolamine)	1	0.3
Supply source	Ralpidos	1	0.3
	Pharmacy	229	67.6
	At home	153	45.1
	Family & friends	3	0.9
	Supermarket	14	4.1
Frequency of use during the last 6 months	Primary healthcare center	4	1.2
	Once	62	15.5
	Twice	78	19.5
	3 times	57	14.3
	>3 times	102	25.5
Average duration of use	Do not remember	40	10.0
	<1 week	263	65.8
	1 week	44	11.0
Chronic disease	>1 week	30	7.5
	No	270	79.6
	Yes	69	20.4
	Hypertension	28	8.3
	Diabetes	27	8.0
	Asthma	9	2.7
	Dyslipidemia	5	1.5
Pain intensity (VAS)	Other 1	13	3.8
	Mean, SD	6.50	2.52
Pain intensity	Mild (0-3)	40	11.8
	Moderate (4-6)	127	37.5
	Severe (7+)	169	49.9

participants, 11.8% admitted using OTC analgesics for mild pain intensity (VAS pain score 0-3), 37.5% for moderate pain intensity (VAS score 4-6) and 49.9% for severe pain (VAS score 7+) (Table 2).

#### *Knowledge and Attitude towards OTC Use and safety*

Among OTC analgesics users, 45.1% declared having self-gained knowledge about the drugs they use, 24.8% acquired knowledge about OTC analgesics from family, 16.5% from previous prescriptions, and 13.0% from the pharmacist; and 44.0% declared to read the drug information pamphlet (Table 3). Regarding circumstances or reasons for OTC use, simple health problem was invoked by majority of the users (64.0%), followed by previous experience with the drug (35.1%) and lack of

time (12.1%) (Figure 2). In case of inefficacy of the OTC analgesic, 64.6% declared to consult the doctor, 8.3% to stop the treatment, and 6.2% to shift to another treatment (Table 3).

Of the users, 58.1% admitted having no knowledge about OTC analgesic side effects; while 26.5%, 13.6% and 6.8% declared being aware of the risk of nephrotoxicity, hepatotoxicity and rash, respectively. Side effects subsequent to OTC analgesic use were reported by 7.1% of the users; with nausea or vomiting (2.7%), rash (2.7%) and stomachache (1.5%) being the most frequent ones. In case of side effect, 3.8% declared consulting a doctor and 3.8% would stop the treatment immediately (Table 3).

**Table 3 (Original): Knowledge and attitude about usage and safety of over-the-counter analgesics**

Parameter	Category	Frequency	Percentage	
Knowledge source about OTC analgesics	Personal knowledge	153	45.1	
	Family	84	24.8	
	Previous prescription	56	16.5	
	Pharmacist	52	13.0	
	Friends	20	5.9	
	Media	15	4.4	
	Other	3	0.8	
Reading treatment brochure	Yes	149	44.0	
	No	190	56.0	
information provided by pharmacist	Yes	100	25.0	
	No	239	59.8	
Reasons for OTC analgesics use	Simple health problem	217	64.0	
	Shortage of transport to care service	35	10.5	
	Lack of time to visit doctor	41	12.1	
	Friend's advice	13	3.8	
	High expense of doctor visit	12	3.5	
	Easy access to treatment	32	9.4	
	Serious condition	4	1.2	
	Treatment already used in the past	119	35.1	
	Attitude if OTC analgesic does not relieve pain symptoms	This never happened	49	14.5
		Consult doctor	219	64.6
Stop the OCT analgesic		28	8.3	
Continue OCT analgesic		19	5.6	
Shift to another treatment		21	6.2	
Associate another treatment		6	1.8	
Increase the dose		1	0.3	
Self-reported Knowledge about OTC analgesics side effects	Yes	142	41.9	
	No	197	58.1	
Knowledge of specific side effects	Nephrotoxicity	90	26.5	
	Hepatotoxicity	46	13.6	
	Rash	23	6.8	
	Abdominal discomfort	21	6.2	
	Cardiac toxicity	21	6.2	
History of side effect on OCT analgesics	Yes	24	7.1	
	No	310	91.4	
	Not sure	5	1.5	
Patient-reported specific side effects	Nausea and vomiting	9	2.7	
	Rash	9	2.7	
	Stomach ache	5	1.5	
	Stomach ulcer	3	0.9	
	Dyspnea	3	0.9	
	Headache	3	0.9	
	Diarrhea	1	0.3	
	Constipation	1	0.3	
	Vertigo	1	0.3	
	Jaundice	1	0.3	
	Others (elevation in BP, insomnia, renal colic)	3	0.9	
Attitude regarding OTC analgesics side effects	Visit doctor	13	3.8	
	Stop treatment	13	3.8	
	Switch to another treatment	3	0.9	
	Reduce dose	2	0.6	
	Continue OTC and associate another treatment to treat symptoms	1	0.3	
	Hospital admission	1	0.3	

**Table 4 (Original): Demographic factors of over-the-counter analgesics use**

Parameter	Category	OTC analgesics use				p-value
		Yes		No		
		Freq.	%	Freq.	%	
Gender	Male	166	83.4	33	16.6	.461
	Female	173	86.1	28	13.9	
Age (years)	Mean, SD	35.05	11.08	36.21	11.55	.455
Nationality	Saudi	240	89.9	27	10.1	.000*
	Non-Saudi	99	75.0	33	25.0	
Marital Status	Married	258	84.0	49	16.0	.280
	Single	71	89.9	8	10.1	
	Divorced	6	75.0	2	25.0	
	Widowed	4	66.7	2	33.3	
Educational Level	Illiterate	14	93.3	1	6.7	.000*
	Writes and reads	11	64.7	6	35.3	
	Primary	24	77.4	7	22.6	
	Middle school	28	73.7	10	26.3	
	Secondary	108	79.4	28	20.6	
	Diploma	23	100.0	0	0.0	
Educational level (5 categories)	University degree	121	93.8	8	6.2	.000*
	High studies	4	80.0	1	20.0	
	Illiterate	14	93.3	1	6.7	
	Write and reads	11	64.7	6	35.3	
	Primary – middle school	52	75.4	17	24.6	
Residency	Secondary	108	79.4	28	20.6	.366F
	University +	148	94.3	9	5.7	
	Jeddah	326	84.5	60	15.5	
	Outside Jeddah	9	100.0	0	0	
Career	Unemployed	150	82.4	32	17.6	.676
	Retired	15	88.2	2	11.8	
	Student	32	86.5	5	13.5	
	Employed	138	86.8	21	13.2	
Family income (SAR)	Up to 3K	59	73.8	21	26.3	.011*
	>3K – 5K	143	85.1	25	14.9	
	>5K – 10K	97	91.5	9	8.5	
	>10K	35	85.4	6	14.6	

#### *Sociodemographic Factors Associated with OTC Analgesics Use*

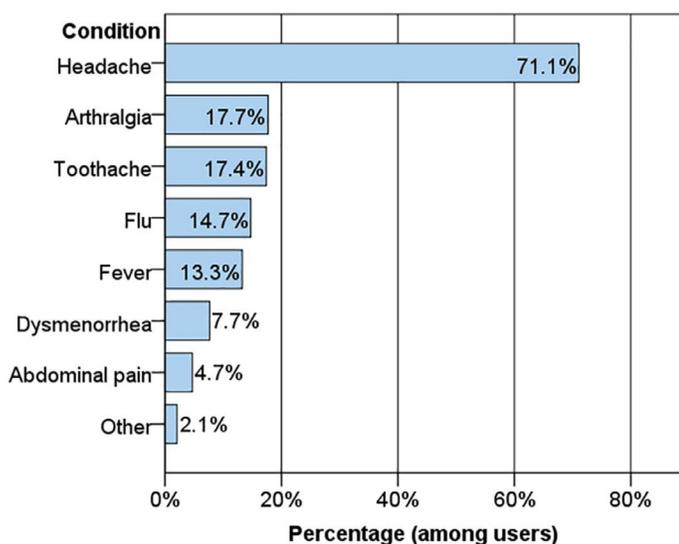
The prevalence of OTC analgesic use was highest among illiterate (93.3%) and highly educated participants (94.3%), by comparison to other educational levels ( $p=0.000$ ). Saudi nationals ( $p=0.000$ ) and those with moderate family income (>3K–5K SAR;  $p=0.011$ ) had the highest prevalence of OTC analgesics use as compared with their counterparts (Table 4). There was no difference in the other sociodemographic factors.

#### *Pattern and Knowledge of OTC Analgesic Usage by Gender, educational level and economic status*

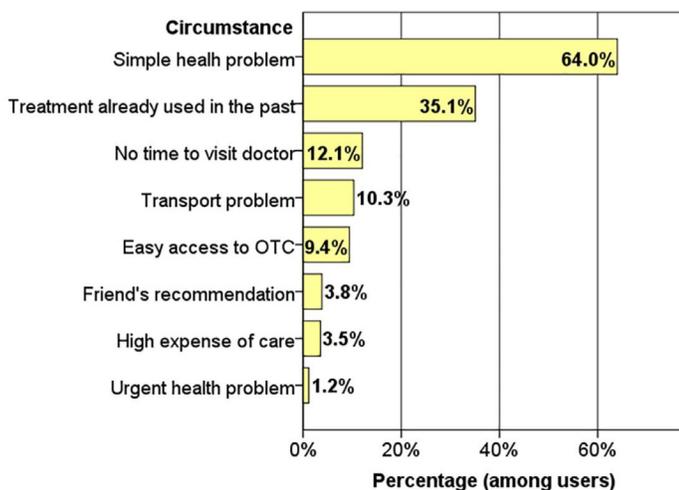
A higher proportion of males declared using OTC analgesics for mild pain (VAS=0-3) as compared to females (15.7% versus 8.2%, respectively;  $p=0.028$ ). No statistically significant difference was observed otherwise regarding pattern of OTC analgesics used including drug used, supply

source, frequency, duration of use, or health condition leading to OTC analgesics use. Differences were observed between the genders regarding knowledge sources; as well as behavior in case of non-efficacy of the OTC analgesic, where more females declared consulting the doctor and less declared shifting to another treatment, as compared to males (results not presented).

Paracetamol was likely to be more frequently used by participants with low educational level ( $p=0.039$ ); whereas ibuprofen was more frequently used by those with higher educational level, but the result was not statistically significant ( $p=0.103$ ). Participants with high educational level had better knowledge about OTC analgesics side effects ( $p=0.000$ ), and better awareness about the risk of hepatotoxicity ( $p=0.001$ ), nephrotoxicity ( $p=0.002$ ) and abdominal discomfort ( $p=0.026$ ). No remarkable



**Figure 1 : Caption:** Bars represent the percentage among OTC analgesics users who declared using OCT analgesics for the given condition. Other conditions include 1 case of biliary colic, 1 chest pain, 1 post-caesarean section, 1 post-delivery pain, 1 renal colic, 1 renal stones, 1 skin allergy. **Reproduction size:** at column width.



**Figure 2 :** Bars represent the percentage among OTC analgesics users who declared using OCT analgesics in the given circumstance. **Reproduction size:** at column width.

correlations with educational level were otherwise observed (results not presented).

Users with moderate-to-high family income (>5K-10K SAR per month) reported more frequently to have a personal stock of OTC analgesics at home as compared to their counterparts ( $p=0.000$ ). Those with high income (>10K SAR per month) had better knowledge about the side effects of OTC analgesics ( $p=0.000$ ), as well as about the related risk of hepatotoxicity ( $p=0.001$ ), nephrotoxicity ( $p=0.000$ ), and abdominal discomfort ( $p=0.004$ ) (results not presented).

## DISCUSSION

The investigation outcomes of the current study showed that OTC analgesics was consumed by 84.8% of the participants, with headache being the leading health condition reported by 71.1% of users. Notable

sociodemographic factors of OTC analgesics use included Saudi nationality, high and very low educational levels, and moderate-to-high family income.

The prevalence and pattern of OTC analgesics varies between countries because of variations in assessment method. In Norway, the prevalence of OTC analgesics use is reported as 47%, which was lower than our finding; however, this was based on past month use.<sup>12</sup> In Netherlands<sup>13</sup> and Spain,<sup>14</sup> the prevalence even lower, reported by up to 30% of the participants. However, the study from Netherlands only assessed usage of NSAIDs, while that from Spain investigated self-medication with analgesics, which may be different from OTC definition and may be over- or underestimating OTC analgesics.

In Saudi Arabia, paracetamol (Panadol) can be purchased in many convenience stores. Most of the studies reported paracetamol as being the most recurrent OTC drug, such as Saeed et al. who reported 35.7% cases of self-medication with paracetamol among university students in Al-Qassim.<sup>15</sup> and Khan et al. who demonstrated that paracetamol is the most requested drug among non-prescribed ones.<sup>16</sup> In Norway, paracetamol is similarly the most frequently used OTC analgesic.<sup>12</sup> All these findings correlate with the results from the current study. The availability and efficacy of OTC paracetamol not only makes it the most popular OTC analgesic, but also makes it frequently associated with risk of misuse or overuse, which may put forth the serious safety concerns.

Ibuprofen and diclofenac were the second most frequently used OTC analgesics, which was similar to the findings of Saeed *et al.*<sup>15</sup> and Khan *et al.*;<sup>16</sup> however, both the authors investigated self-prescription and self-medication of all type of medicine and not only analgesics. In Netherlands, the prevalence of the use of NSAIDs was estimated to be 30% in the general population and 13% in individuals with high risk of NSAIDs adverse effects,<sup>13</sup> which is considered to be high with regards of the related risks.

Saeed et al. reported headache as the major symptom leading to self-medication among male university students (59.9%), which is similar the present study results.<sup>15</sup> The association of self-medication with headache, especially migraine, has long been considered as an issue, as it exposes to addiction and rebound headache syndrome, besides liver and gastrointestinal toxicity.<sup>17</sup> Further, the use of OTC analgesics may delay the appropriate care and expose to treatment interactions.<sup>18</sup> On the other hand, it was observed that access to OTC analgesics combined with specific education program for patients with migraine improved their quality of life and enhanced migraine relief.<sup>19</sup> These observations demonstrate that both safety and efficacy of OTC analgesics are conditioned by adequate patient's education and knowledge about the appropriate usage of these drugs.

Similar to present study results, A study from Riyadh reported that minor symptoms (54%), time saving (40%) and knowledge about the treatment required (40%) were the major reasons for OTC drugs use.<sup>20</sup> All these factors are dependent to consumer's own judgment and interpretation, and are greatly influenced by knowledge and attitude as well as previous experience with both the condition and the drug efficacy and safety.<sup>21,22</sup> Further, there is a strong relationship between health beliefs and frequency of OTC medicine use as well as the choice of the drug.<sup>23</sup>

The present study results provide a picture of the level of awareness about the eventual harmfulness of these medicines, which may condition exposure to overuse and misuse. Less than half of users declared having knowledge about side effects and a minority were aware about nephrotoxic, hepatotoxic or allergic risks. The risk-benefit ratio of OTC analgesics is problematic from three major perspectives, which are: 1) the known drug health risks and side effects involving hepatic and gastrointestinal systems; 2) the frequent absence of medical supervision; and 3) the great availability of these drugs from a variety of channels.<sup>24,25</sup> We

conclude that the level of awareness about health risks is inadequate in the study population and should be more extensively investigated to determine the need for information and specific information to improve the risk-benefit ratio of OTC analgesics.

Similar to our findings, in Spain, analgesics self-medication was reported to be more practiced by younger, male, and highly educated population.<sup>14</sup> In Australia, females and younger participants were more frequently reported as regular users,<sup>26</sup> while no significant difference across genders and age were found in the present study. The high usage rate among highly educated and illiterate participants may result from opposed attitudes, which are knowledge about the drugs among highly educated and poor awareness among illiterate ones.

Analysis from this study stress the importance of safety in OTC analgesics use and its correlation with knowledge and awareness. Consequently, the physician-patient communication regarding OTC should be encouraged, as it has great contribution on patient's education and appropriate use of the OTC medicine.<sup>27</sup>

This study involves patient-reported side effects, which may not be an accurate method as this involves recall bias in addition to eventual difficulty to correlate the side effect with the OTC analgesic use. Other limitation is the self-assessment of knowledge about health risks related to misuse without verification of actual knowledge and understanding of the enumerated risks.

## CONCLUSION

There is an alarming prevalence of OTC analgesics use among patients attending PHC centers in Jeddah, with paracetamol being the most frequently used drug and headache being the most frequent cause. Minor health problems and past use of the drug are the two major reasons of using OTC analgesics. This high usage rate is combined with inadequate level of awareness about the associated health risks, which raises several concerns about consumers' safety. Awareness and knowledge of OTC analgesics users should be further investigated to determine the need for information for specific or large-scale populations.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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