

Evaluation and awareness of over the counter use of non-steroidal anti-inflammatory drugs

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ABSTRACT

Objectives: Non-steroidal anti-inflammatory drugs are among the drugs with the highest prevalence of use (with or without prescription). While a notable percent of patients have incomplete knowledge about appropriate use of over the counter drugs. The aim of the current study was to evaluate the pattern of over the counter use of non-steroidal anti-inflammatory drugs and also the public knowledge about different aspects of over the counter use of non-steroidal anti-inflammatory drugs such as adverse effects, proper dose and drug interactions with concurrent medications.

Material and methods: The in-charge pharmacists of the 10 pharmacies asked purchaser the important questions about OTC use of NSAIDs and then recorded the responses using face-to-face interviewing. The in-charge pharmacists interviewed with 600 NSAIDs purchasers during the study.

Results: More than half of all the purchasers received non-steroidal anti-inflammatory drugs use recommendation either by physicians or pharmacists. But less than 35% of the purchasers had been informed by the physicians or pharmacists about drug interactions, adverse effects and proper use of non-steroidal anti-inflammatory drugs. It was found 63.8% of the customers used non-steroidal anti-inflammatory drugs as needed and 23.3% of them used usual dose. In addition, 92.5% and 79.2% of the consumers were not aware of non-steroidal anti-inflammatory drugs drug interactions and side effects, respectively. The most prevalent concurrent medical conditions were cardiovascular diseases (12.2%).

Conclusion: The level of public knowledge regarding non-steroidal anti-inflammatory drugs was low.

INTRODUCTION

Self-medication is one of the cornerstones of today's self-care. Purchasing over the counter (OTC) drugs is promoted through many reasons. One reason is that patients might prefer quicker access to medication especially when the patients want to relieve their pain. Another reason is that by OTC use patients do

not need to pay physician's consultation fee, so it will lower the healthcare costs. Physical disabilities, constant time pressure of today's lifestyle and increasing availability and promotion of pharmaceutical products are noted as other reasons (Hughes *et al.*, 2001; Sharma *et al.*, 2015). Analgesics and in particular non-steroidal anti-inflammatory drugs (NSAIDs) are among drugs with the highest prevalence of use (with or without prescription). These medications can treat conditions such as mild to moderate inflammatory pain, rheumatoid arthritis, dysmenorrhea, migraine, headache, fever and many other ailments (Majithia *et al.*, 2013; Pountos *et al.*, 2011).

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OTC consumption of these drugs within defined limits is considered to be safe and beneficial as long as patients are capable of diagnosing their health conditions correctly and have the ability to extract necessary information like warnings and contraindications from patient's information leaflet (Wood & Brass, 2001). Also, it is crucial to bear in mind that OTC consumption of these drugs, even within safe and limited dosage, in different health conditions, may have potential risks (Singh, 2000; Trelle *et al.*, 2011).

There are some studies with stated concerns about perils of unsupervised NSAIDs consumption owing to variety of reasons such as exceeding maximum recommended dosage particularly in patients with high risk of developing adverse drug reactions (Koffeman *et al.*, 2014), general belief about OTC drugs safeties, lacking knowledge of NSAIDs drug interactions (Wilcox *et al.*, 2005), side effects (Jande *et al.*, 2013), and precautions due to concurrent medical conditions. Thus, considering the high frequency of OTC NSAIDs use, patient education about drug interactions, contraindications and other issues has been recommended (Stosic *et al.*, 2011). Furthermore, a study conducted in Iran confirmed analgesics as medications with the highest demand in pharmacies. Additionally, it was found a notable percent of patients had incomplete knowledge about appropriate use of OTC drugs (Sahebi and Vahidi, 2009).

NSAIDs usage is associated with gastrointestinal problems, kidney damages, asthma worsening in affected patients, increasing risk of post-surgery and post-partum bleeding, erectile dysfunction, and complications regarding conception and pregnancy (Sharma *et al.*, 2015). Important drug interactions occur when these medications are used with several drugs such as selective serotonin reuptake inhibitors (SSRIs), anticoagulants, antiplatelet drugs (Goldstein and Cryer, 2015) and antihypertensive drugs (Floor-Schreuder *et al.*, 2015). Also, there has been increased risk of adverse events in patients with underlying conditions namely, renal, gastrointestinal and cardiovascular diseases (Harirforoosh *et al.*, 2014).

Since there were a limited number of studies in Iran that focused on the non-prescription use of NSAIDs, the present study was designed. The aim of the current study was to evaluate the pattern of OTC use of NSAIDs and also the public knowledge about different aspects of OTC use of NSAIDs such as adverse effects, proper dose and drug interactions with concurrent medications.

MATERIAL AND METHODS

This cross-sectional study was performed in Kerman, a city located in the south east of Iran, during November 2015. The study protocol was approved by the ethical committee of Kerman University of Medical Sciences. There were approximately one hundred community pharmacies in Kerman. Ten managers of the pharmacies accepted to participate in this study.

The in-charge pharmacists of the mentioned 10 pharmacies accepted to perform this study. The important

questions about OTC use of NSAIDs were chosen based on literature review such as Wilcox *et al.* (2005) and Saengcharoen *et al.* (2016) studies and expert opinion (clinical pharmacists). The mentioned 10 pharmacists were fully trained to perform interviews and were evaluated by a clinical pharmacist. After obtaining oral consent, the in-charge pharmacists of the 10 pharmacies asked OTC purchasers of NSAIDs the chosen questions and then recorded the responses using face-to-face interviewing. Each interview took about 15 minutes. The in-charge pharmacists interviewed with clients who came to pharmacy and requested OTC NSAIDs between 4 to 8 p.m. from Saturday to Wednesday during 4 weeks.

The questions included the following issues: demographic information (gender, age, occupation, and level of education), name of NSAID, dosage form, indication, source of information, awareness of dosing, side effects, drug interactions and concurrent medical conditions, and pregnancy consideration.

In addition, UpToDate® (UpToDate, Waltham, MA, USA, available from <http://www.uptodate.com>), was used as drug-information reference for each NSAID. The correct dose of NSAIDs was also determined for each indication. It was focused on harmful drug interactions and side effects of NSAIDs. Also, only concurrent medical conditions in which NSAIDs must be used with caution were considered.

The statistical package of social science (SPSS) version 20 was used for all the analyses. Descriptive analysis was used for all the variables. Chi-square and post-hoc tests, using standardized residuals, were utilized to determine the relationship between the qualitative variables. The p value less than 0.05 was considered as statistically significant.

RESULTS

The in-charge pharmacists interviewed with 600 NSAIDs purchasers during the study. The demographic characteristics of all the participants are presented in table 1. Furthermore, the common purchased NSAIDs in descending order were ibuprofen (195 (32.5%)), diclofenac (94 (15.7%)), mefenamic acid (94 (15.7%)), naproxen (45 (7.5%)), aspirin (44 (7.3%)), piroxicam (31 (5.2%)), meloxicam (27 (4.5%)), indometacin (23 (3.8%)), celecoxib (22 (3.7%)), ketorolac (17 (2.8%)), and tolmetin (8 (1.3%)). Also, two or more oral dosage forms of different NSAIDs were requested by 43 (7.2%) of the participants.

In addition, the reasons for using NSAIDs in descending order were musculoskeletal pain (249 (41.5%)), headache (131 (21.8%)), toothache (90 (15%)), dysmenorrhea (66 (11%)), antiplatelet (29 (4.8%)), colic pain (26 (4.3%)), and fever (9 (1.5%)). Also, the requested dosage forms in descending order were solid oral (518 (86.33%)), topical (28 (4.7%)), suppository (25 (4.2%)), injection (21 (3.5%)), and suspension (8 (1.3%)). The average number of purchased NSAIDs (solid oral dosage forms) was 13.09 ± 8.33 .

Of all the clients, 208 (34.7%) clients were not the NSAIDs consumers, and the mentioned clients only purchased the

NSAIDs for another person. Moreover, the past use of NSAIDs was reported by 504 (84%) clients, and 107 (17.83%) had experienced side effects in the past use of NSAIDs. Gastrointestinal (98 (16.33%)), cardiovascular (8 (1.33%)), and respiratory (1 (0.17%)) events were noted as common experienced side effects. The answer of clients to each asked question is presented in table 2. Additionally, the consumed dose of NSAIDs in comparison with the usual dose of NSAIDs for each indication was determined as follow: as needed (383 (63.8%)), less than

usual dose (76 (12.7%)), usual dose (140 (23.3%)), and more than usual dose (1 (0.2%)). Furthermore, the relation between demographic data and having information about NSAIDs drug interactions, NSAIDs adverse effects and how to use NSAIDs are also presented in table 1. It was found the level of education of the participants had statistically significant effects on having information about NSAIDs drug interactions ($p= 0.001$), NSAIDs adverse effects ($p= 0.003$) and how to use NSAIDs ($p= 0.013$). The doctorate clients made these significant differences.

Table 1: The demographic characteristics of all the participants.

Characteristics	Participants (Number (percent))	p value*		
		Knowledge on NSAIDs** drug interactions	Knowledge on NSAIDs adverse effects	Knowledge on How to use NSAIDs
Gender				
Male	293 (48.8%)	0.285	0.834	0.269
Female	307 (51.2%)			
Age				
Less than 50 years	458 (76.3%)	0.621	0.738	0.278
Equal or more than 50 years	142 (23.7%)			
Education				
Illiterate	19 (3.2%)			
Underhigh school diploma	83 (13.8%)			
High school diploma	166 (27.7%)	0.001	0.003	0.013
Bachelor's	130 (21.7%)			
Master's	26 (4.3%)			
Doctorate	15 (2.5%)			
Missing/Invalid	161 (26.8%)			
Occupation				
Student	95 (15.8%)			
Self-employed	109 (18.2%)	0.931	0.158	0.1
Employee	163 (27.2%)			
House-hold	94 (15.7%)			
Missing/Invalid	139 (23.2%)			

*Based on chi-square test

**NSAIDs: Non-steroidal anti-inflammatory drugs

Table2. The clients answer to each asked question related to NSAIDs *use

Questions	Participants (N (%))
Who recommended the use of this drug?	
Physician	216 (36%)
Pharmacist	124 (20.7%)
Internet	9 (1.5%)
Relatives and friends	183 (30.5%)
Others	68 (11.3%)
Awareness of NSAIDs related drug interactions	
Yes	45 (7.5%)
No	555 (92.5%)
Concurrent medication	
No	366 (61%)
Yes	231 (31.5%)
Missing/Invalid	3 (0.5%)
If yes, which categories	
Antihypertensive drugs	73 (12.2%)
Antidepressant drugs	31 (5.2%)
Aspirin	5 (0.8%)
Warfarin	0
Awareness of NSAID interactions with a concurrent drug from the mentioned categories	
Yes	21 (3.5%)
No	88 (14.67%)
Awareness of NSAID side effects	
No	475 (79.2%)
Yes	125 (20.8%)
If yes, which side effects	
Cardiovascular	38 (6.33%)
Gastrointestinal	125 (20.83%)
Renal	4 (0.67%)

Concurrent medical conditions	
No	449 (74.8%)
Yes	151 (25.2%)
If yes, which one	
Cardiovascular	73 (12.2%)
Gastrointestinal	36 (6%)
Renal	16 (2.6%)
Respiratory	11 (1.8%)
Others	15 (2.5%)
Awareness of how to use NSAIDs	
No	328 (54.67%)
Yes	272 (45.33%)
Previously had been informed about drug interactions, adverse effects and how to use NSAIDs by	
Physician	105 (17.5%)
Pharmacist	102 (17%)
Concurrent use of topical and systemic NSAIDs	
No	493 (82.2%)
Yes	107 (17.8%)
Awareness of the risks associated with NSAIDs use during pregnancy	
Yes	56 (9.3%)
No	542 (90.3%)
Missing/Invalid	2 (0.3%)

* NSAIDs: Non-steroidal anti-inflammatory drugs

DISCUSSION

In the current study, it was found that females received OTC NSAIDs more than males and 76.3% of the consumers were under 50 years old. The higher use of OTC NSAIDs in female and younger patients has been reported in previous studies (Duong *et al.*, 2014; Sarganas *et al.*, 2015). It was also found Ibuprofen was the most commonly purchased NSAIDs and this fact was similar to the results of other studies in Germany, France and the United States (Duong *et al.*, 2014; Sarganas *et al.*, 2015; Wilcox *et al.*, 2005). In the present study, the education level of most of OTC NSAIDs purchasers were more than diploma, and, among all the participants, the doctorate clients had more information about NSAIDs. It was previously shown that the higher the socioeconomical level, more the consumption of OTC NSAIDs (Sahebi and Vahidi, 2009).

In the present study, it was found the most common reason for OTC use of NSAIDs was musculoskeletal pain and also 63.8% of the consumers used NSAIDs as needed and 23.3% of them used usual dose. In addition, 79.2% of the participants were not aware of NSAIDs side effects. In a similar study, conducted by Wilcox *et al* in the United States, it was reported that musculoskeletal pain was the most common reason for OTC use of NSAIDs, and 73% of the users consumed them as needed and 57% consumed the exact dosage. It was also found 60% of OTC users were not aware of NSAIDs side effects (Wilcox *et al.*, 2005). In another study undertaken in Scotland, Porteous *et al* found that the most common reason for using nonprescription analgesics was headache (59%), and also the researchers warned about inappropriate use of nonprescription analgesics (Porteous *et al.*, 2005). Moreover, it was found 92.5% of OTC consumers of NSADs were not aware of NSAIDs drug interactions. It should be noted that 18.2% of the participants were using medications that had potential drug interactions with NSAIDs. Indermitte *et al* investigated the awareness of regular customers concerning

potential drug interactions between their prescribed medications and purchased OTC drugs in Switzerland. It was found 46.8% of their participants were aware of these potential drug interactions. The prescribing physicians and the community pharmacists had informed 47.3% and 25.6% of the participants, respectively (Indermitte *et al.*, 2007). This study highlighted the essential roles of physicians and pharmacists to increase patients' awareness of potential drug interactions.

In the present study, more than half of all the purchasers received NSAIDs use recommendation either by physicians or pharmacists. But less than 35% of the purchasers had been informed by the physicians or pharmacists about drug interactions, adverse effects and proper use of NSAIDs. So the majority of the present study participants purchased NSAIDs without professional guidance. This finding could be explained by following reasons. First, pharmacists as the last health professionals that patients meet play a vital role in consultations of non-prescription medicines (van Eikenhorst *et al.*, 2016). It was reported that pharmacists provided higher quality information regarding OTC use of medications (Sahebi and Vahidi, 2009). But during rush-hours, pharmacists are too busy to evaluate patients' conditions and to provide them with necessary information about proper medication use (Cooksey *et al.*, 2002). Second, this false assumption that OTC medications are harmless might lead to carelessly unsupervised usage of NSAIDs (Wilcox *et al.*, 2005) and might cause customers refrain from getting advice.

In the current study, a notable percent (17.8%) of the purchasers mentioned concurrent use of topical and oral form of NSAIDs. Also, 7.2% of them requested two or more oral dosage forms of different NSAIDs. Clinard *et al* evaluated the risk of some selected adverse effects resulted from concomitant usage of two or more NSAIDs, whether OTC or prescribed ones. It was found that the patients who consumed two or more NSAIDs were more prone to GI bleeding, renal and hepatic injuries (Clinard *et al.*, 2004). In the present study, the most prevalent concurrent

medical conditions were cardiovascular diseases (12.2%). Only 6.33% of the participants knew about cardiovascular side effects of NSAIDs, and 1.33% of them had experienced these side effects in the past. In a study performed by Adams *et al* in Australia, it was shown that 16 % of NSAIDs users had hypertension, and 20 % of them had cardiovascular complications (Adams *et al.*, 2011).

In the current study, 16.33% of the participants reported gastrointestinal complications as experienced adverse effects in the past uses, 6% of them noted gastrointestinal diseases as concurrent medical conditions and 20.83% knew about gastrointestinal side effects of NSAIDs. In a study conducted by Thomas *et al*, it was found the number of OTC users of NSAIDs that experienced gastrointestinal complications was twice more than the number of non-users (Thomas *et al.*, 2002).

Aspirin and NSAIDs that inhibit cyclooxygenase-1 can cause aspirin-exacerbated respiratory disease in a small percentage of general population (Lee and Stevenson, 2011). In the present study, the patients with underlying respiratory conditions were 1.8%. Also, just 0.17 % of the participants had experienced respiratory side effects in the past. But despite this weak possibility of serious consequences, still caution should be exercised. Also, it was found 2.6% of the participants were those with underlying kidney problems, and only 0.67% of the participants knew about renal side effects of NSAIDs. While it is recommended to avoid NSAIDs use in most patients with chronic kidney disease (CKD), OTC use of NSAIDs has been reported by nearly 7.5% of population with mild to severe CKD in the United States. However, awareness of this comorbidity did not reduce the use of NSAIDs in the mentioned population (Plantinga *et al.*, 2011).

In the current study, only 9.3 % of the participants were aware of pregnancy considerations regarding NSAIDs use. In a study performed by Stosic *et al*, 37.3% and 19.8% of female participants claimed awareness of risks of NSAIDs use during pregnancy and near the time of conception, respectively (Stosic *et al.*, 2011).

The results of the present study demonstrated that the customers did not have necessary information about NSAIDs use, so educating patients regarding NSAIDs use seems crucial. The pivotal role of pharmacists in educating patients should not be ignored (Pai, 2015). The current study had some limitations. The number of pharmacies managers who agreed to participate in this study was low (10 among nearly 100). This might lead to loss of a large number of NSAIDs purchasers. Also, in this study, a notable number of purchasers bought NSAIDs for someone else, and this caused invalid, insufficient and missing data. Additionally, the responsible pharmacists recorded the purchasers' data, but sometimes the pharmacists missed some purchasers because of their high workload.

CONCLUSION

It was concluded the level of public knowledge regarding non-steroidal anti-inflammatory drugs was low. And the OTC users

of NSAIDs did not have sufficient information about different aspects of NSAIDs use such as proper dose, side effects, drug interactions, and effects on underlying diseases.

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