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Awareness of paracetamol overuse headache among Saudi's population in Taif city, Saudi Arabia

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ABSTRACT

Background: Medication overuse headache has been identified as a significant issue among headache patients which can be caused mostly by overuse of mild analgesics, such as paracetamol. *Objective:* The aim of this study was to evaluate and assess the awareness of paracetamol overuse headache among Saudi's population in Taif City-Saudi Arabia. *Methodology:* A cross-sectional descriptive study was conducted. An electronic questionnaire was used for data collection. Data were collected and analyzed using SPSS program version 22. *Results:* In our study 44% of participants have experienced chronic headache, most of them have it less than five days/ month and 90% of them reported using paracetamol to relieve the headache. Moreover, knowing the maximum permitted daily dose of paracetamol was only recognized by 135 (35%) of participants. whether paracetamol overuse can cause headache was affirmed in 54 (14%) of participants. 42.3% only of the participants are aware of the side effects. The chronic headache was listed as the third most common side effect. The possibility that overdoses of paracetamol can because headache was proven to be statistically significant correlated with age range (18-24 years), with the knowledge concerning taking paracetamol every day and knowing the maximum daily dose of paracetamol, knowledge regarding all side effects. All these listed factors are statistically significant ($p < 0.05$). *Conclusion:* This study showed a limited level of knowledge and awareness regarding headache induced by paracetamol overdose among participants from Taif City in Saudi Arabia, which highlighted the need to increase the awareness in our community.

Keywords: Medication overuse, acetaminophen, overuse headache, paracetamol, over the counter, analgesics.

1. INTRODUCTION

Headache is a major and most common public health problem, given the high

number of disabilities and the associated financial costs to both the individual and society (Kristoffersen and Lundqvist, 2014). Out of the 301 acute and chronic illnesses tracked by the Global Burden of Disease (GBD) studies, two forms of headache are ranked among the highest prevalence forms: Tension headache (TH) and migraine (Westergaard et al., 2016). Headaches are classified as primary (idiopathic) or secondary in the International Classification of Headache Disorders 3rd beta edition (ICHD-III). Primary (idiopathic) headaches are those that have no known origin, whereas secondary headaches are those that are thought to be caused by other illnesses or external influences (e.g., surgery, trauma, toxic effects of substances or medications or infection (Kristoffersen and Lundqvist, 2014). Medication overuse headache (MOH) is a type of chronic daily headache (CDH) that caused by excessive use of migraine abortive medications. The main groups of medicines implicated in the origin of MOH are acetaminophen, combination analgesics (caffeine-combinations), opioids, barbiturates (butalbital), non-steroidal anti-inflammatory drugs and trip tans. In the past MOH was known as rebound headache, drug- induced headache or medication misuse headache (Silva and Lake, 2013).

MOH can be either primary or secondary, that occurs 15 or more days a month, for 4 or more hours a day, for at least three months. MOH is characterized by an increase in the frequency and severity of headaches or migraine attacks, as well as increased sensitivity to the triggers that trigger these episodes (Thorlund et al., 2016). Mechanisms of MOH remain unknown. However, rather than the total amount of medicine utilized, the number of analgesic-free days is thought to be important in the development of MOH (Lai et al., 2014). MOH is a common condition that represents a known and difficult clinical problem. More than 60 million people are affected worldwide. In addition, it is a debilitating disease that poses a significant burden to individuals and socio-economic challenges to society (Carlsen et al., 2020). Also, overuse of medications was discovered to be a significant risk factor for the primary headaches to be chronic (Ashina and Jensen, 2010).

MOH is a serious problem among headache patients all over the world with a prevalence rate of 1–1.5 percent in the general population (Schmid et al., 2013). MOH was found in 20% of the CDH group, accounting for 0.3% of the total study population (Silva and Lake, 2013). According to studies conducted mostly at tertiary care headache clinics migraines and to a lesser extent, individuals with tension-type headaches are at risk of their headaches worsening if they take acute relief medicine on a frequent basis (Schmid et al., 2013). MOH can be as; common as 70% among referred patients in specialized headache centers and when its high socioeconomic impact is considered (work absenteeism, recurrent emergency room visits, hospital admissions and unnecessary diagnostic tests). MOH is one of the costliest neurological disorders (Silva and Lake, 2013).

Patients and the healthcare system as a whole gained from easy access to proven safe and effective medicines. Self-medication, on the other hand, is only safe and effective if users are aware of the drug's indications, proper usage, expected outcomes and probable side effects. Acetaminophen, also known as paracetamol, is a weak analgesic that is widely used globally. It is considered one of the over-the-counter medications at all levels of the health-care system (Dorji and Pongpirul, 2018). Because of its efficiency, low occurrence of adverse effects and improved patient tolerance, paracetamol is a mild analgesic that is widely preferred (Graham et al., 2013). It was found that paracetamol is the most common over-the-counter medication in Riyadh city, in Saudi Arabia, represents 47.3% in comparison to other over-the-counter drugs (Aldeeri et al., 2018). Little is known about level of awareness of the general population in Taif city about paracetamol overuse headache, so this study was conducted aiming to assess awareness among general population about paracetamol overuse headache.

2. SUBJECTS AND METHODS

The study was conducted in Taif city, which is located in the western part of the Kingdom of Saudi Arabia. The study was carried out during the period from 1st of November 2021 to the end of February 2022. Male and females' Saudi population aged 18-60 years old who are living in Taif were included in the study to detect pre-determined objectives.

A cross-sectional descriptive study was carried out on the participants to find out the predetermined objectives. The simple random sampling technique was used. A Raosoft sample size online calculator was used to calculate the sample size. Assuming that, a 50 % response distribution was used, with a 5% margin of error and a 95 % confidence interval. So, the total of 385 people was selected to participate in the study. The responses were excluded if they are from (1) those under the age of 18 and those above the age of 60, (2) those who are non-Saudi and (3) those who do not live in Taif, Saudi Arabia. An online survey had been conducted among 385 adult residents in Taif City. A translated Arabic electronic questionnaire was used to collect the data. We asked each participant to fill this questionnaire.

The questionnaire included socio-demographic data including gender, age groups, educational level, socioeconomic status and other questions to assess knowledge and perception of participants about the paracetamol overuse headache including questions about headache and medications used in treating the headache and questions related to frequency, duration and severity of the

headache and frequency of paracetamol usage. The structured questionnaire was developed, pretested and validated in a pilot study on a small number of participants about 20-30.

Data were entered on the computer using the "Microsoft Office Excel Software" program (2016) for windows. Then the data transferred to the Statistical Package of Social Science Software (SPSS) program, version 22 (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.) to be statistically analyzed. Mean and standard deviation were calculated for quantitative data. Qualitative data were presented as frequencies and percentages. Chi-square test was used to compare the two qualitative groups with baseline characteristics. P-value of <0.05 was considered to show a statistically significant relationship between the different groups. All approvals required to conduct the research were obtained from the research ethics committee of Taif University with approval letter number (43-085). Each participant in this study was oriented and taught about the purpose of the study and that the information used for conducting the research only and consent was taken from each participant before participation in the study.

3. RESULTS

A total of 385 participants were enrolled in this study and had completed a self-administered questionnaire with a response rate of 100%. The participants provided answers to all the questions.

Table 1 Socio-demographic characteristics of studied participants

Variable		NO. (%)
Gender	Males	99 (25.7)
	Females	286 (74.3)
Age group	18-24	267 (69.4)
	25-29	23 (6.0)
	30-39	28 (7.3)
	≥40	67 (17.4)
Education state	Elementary	4 (1.0)
	Intermediate	3 (0.8)
	Secondary	75 (19.5)
	University and higher	303 (78.7)
Employment state	Students	267 (69.4)
	Not employed	23 (6.0)
	Employed in health sector	4 (1.0)
	Employed in other sector	44(11.4)
	Retired	24(6.2)
	House-wife	23(6.0)
Socioeconomic status	High income/month (>10000 SR)	93 (24.2)
	Middle income/month (5000-10000 SR)	73 (19)
	Low income/month (<5000 SR)	219 (56.9)

Most participants were in the age group range of 18-24 years old (69.4%), with the highest percentage of females' participants (74.3%). 78.7% of the participants had an educational state described as university and higher, 69.4% of the participants had an employment state described as Students and 56.0% of the participants had low income/month (Table 1).

Table 2 Association of chronic headache with paracetamol use among participants

Variable		Number	Percent
Have you experienced chronic headache?	Yes	171	44.4%
	No	214	55.6%
Duration of headache in days/month	< 5	262	68.1%
	5-10	61	15.8
	10-15	25	6.5%

	>15	37	9.6%
Taking paracetamol everyday cause headache	Yes	113	29.3%
	No	272	70.6%
Take paracetamol for consecutive 3 days	Yes	161	41.8%
	No	125	32.4%
	I don't know	99	25.7%
Number of paracetamol pills (500 mg) taken at one time?	One pill	229	59.5
	Two pills	139	36.1
	Three or more pills	17	4.4
Know maximum daily dose of paracetamol	Yes	135	35%
	No	250	64.9%

The number of participants who reported chronic headache was 171 (44.4%). The duration of the headache (>5days) was reported by 262 (68.1%) of participants. The use of paracetamol everyday cause headache was reported by 113 (29.3%) participants. Moreover, a large number of participants reported using paracetamol for consecutive 3 days 161(41.8%). The percentage of participants using one tablet of paracetamol (500 mg) at one time was the highest 229 (59.5%) in comparison to the use of two tablets or more. Lastly, 135 (35%) of participants don't know what the maximum dose of paracetamol (Table 2). 67.0 % of participants don't know if overdose of paracetamol can cause the headache (Figure 1). Regarding side effects of paracetamol, most of participants chose a loss of appetite as a possible side effect in comparison to other side effects, followed by stomach pain, nausea and chronic headache (Figure 2).

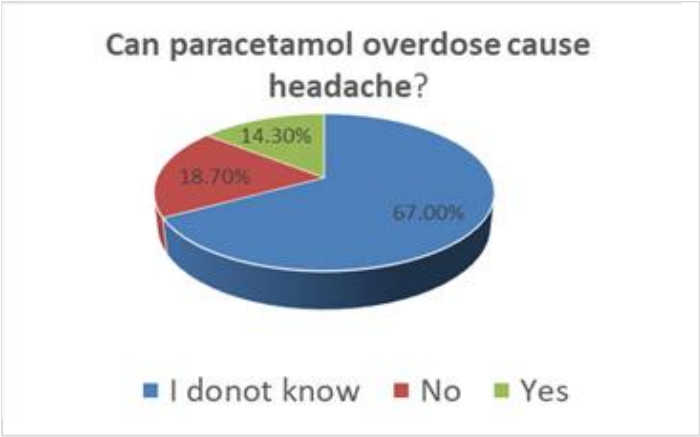

Figure 1 Paracetamol overuse and headache

Most of participants 336 (87.8%) reported using of paracetamol as pain killer or antipyretic, 347 (90.1%) use paracetamol to relief a headache especially severe headache 191 (49.6%). On the other side, most participants 191 (49.6%) take paracetamol without prescription and 222 (57.7%) of participants do not aware side effects of paracetamol. Regarding attitude of participants towards paracetamol induced headache, 225 (58.4%) and 124 (32.2%) of participants were neutral in relation to paracetamol can cause headache or worsen the headache and follow physician instructions when taking paracetamol, respectively (Table 3).

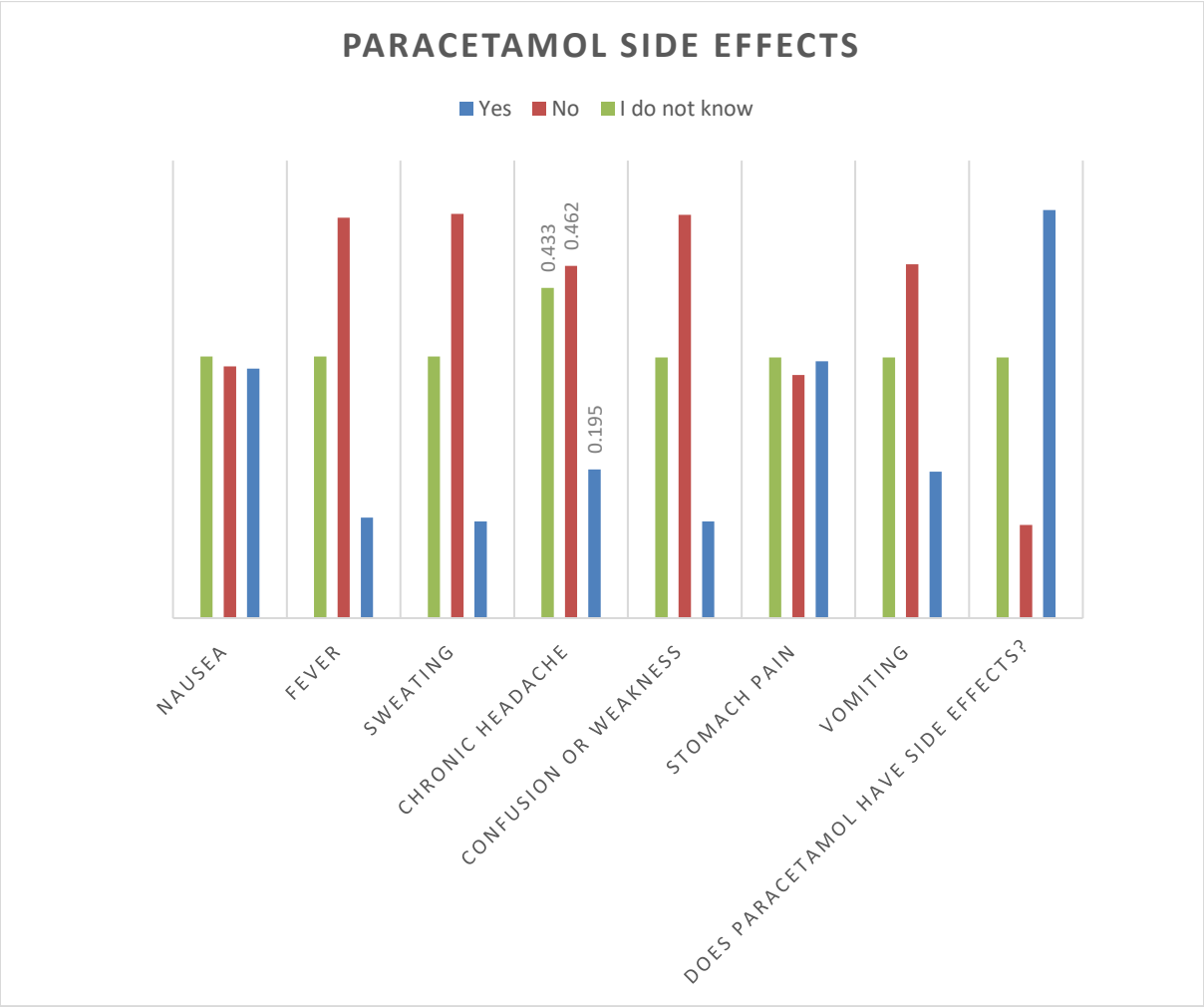

Figure 2 Awareness about side effects of paracetamol among study participants

Table 3 The knowledge and Attitudes of paracetamol among study participants

Variables		No.	%
Do you use paracetamol as a pain killer or antipyretic?	Yes	336	87.3%
	No	49	12.7%
Do you use paracetamol to relief a headache?	Yes	347	90.1
	No	38	9.9
Do you use paracetamol before occurrence of the headache for prevention?	Yes	103	26.8
	No	282	73.2
Type of headache indicated for paracetamol	Mild headache	22	5.7
	Severe headache	191	49.6
	Any type of headache	172	44.7
Have you taken paracetamol pills for more than 15 days/month for over 3 months?	Yes	59	15.3
	No	326	84.7
Do you use paracetamol by prescription	Prescription	17	4.4
	Without prescription	191	49.6
	Both	177	46.0
Do you think it is fine to take paracetamol without a prescription?	Yes	357	92.7
	No	28	7.3
Are you aware paracetamol side effects?	Yes	163	42.3
	No	222	57.7
Paracetamol overuse could worsen the	Strongly agree	50	13.0

headache and also cause chronic headache	Agree	70	18.2
	Neutral	225	58.4
	Disagree	29	7.5
	Strongly disagree	11	2.9
One should follow the physician's instructions when taking paracetamol pills	Strongly agree	114	29.6
	Agree	107	27.8
	Neutral	124	32.2
	Disagree	34	8.8
	Strongly disagree	6	1.6

Table 4 Cross tabulation of the differences in the participant's responses of the questionnaire measured with Chi-Square test

		Can overdose paracetamol cause headache?		Chi-Square value	P value
		Yes	No		
Gender	Male	11	88	0.939	0.402
	Female	43	243		
Age	18-24	46	221	7.744	0.052
	25-29	2	21		
	30-39	1	27		
	>=40	5	62		
Educational Level	elementary	0	4	1.391	0.708
	intermediate	0	3		
	secondary	12	63		
	university and higher	42	261		
Employment State	Students	46	221	8.075	0.152
	not employed	2	21		
	employed in health sector	0	4		
	employed in other sector	4	40		
	retired	1	23		
	house wife	1	22		
Socio economic Status	high income/month (>10000 SR)	12	81	0.166	0.920
	Middle income/month (5000-10000 SR)	10	63		
	low income/month (<5000 SR)	32	187		

The factor affecting the awareness about paracetamol overuse headache with significant difference was age, where age group 18-24 years old participants were more aware than other age groups ($p>0.05$), other factors, university and higher level of educations but with insignificant difference (Table 4).

4. DISCUSSION

Medication overuse headache has been identified as a significant issue among headache patients. The medication overuse headache can be caused by overuse of mild analgesics, such as paracetamol. As the number of population consuming paracetamol as analgesic increases, the need of these population for enhancing their knowledge about the consequences of paracetamol consumption increases. Evaluated assessment of knowledge and awareness concerning paracetamol overuse headache among our sample participants showed that most of our participants use the medication as a painkiller, antipyretic or to relieve headache, especially primarily severe types. This finding was in consistent with study done in 2021 (Alharbi et al., 2021). Our results and responses from our participants, who are mostly 78.7%, are university students or higher, reported limited levels of knowledge and awareness regarding headache induced by paracetamol overdose intake, through closed-ended questions, multiple choice

responses from the given questionnaire; hence, the limited awareness could be higher in fact in the general population compared to our small sample size.

Regarding the side effects of paracetamol, despite of that more than half (53.5%) of them agreed that paracetamol has side effects, results have shown that chronic headache was listed as the third most common side effect after stomach pain and nausea. Many of them (70%) have affirmed that using paracetamol every day doesn't cause a headache and also (41%) agreed that it can be given for three consecutive days. In comparison with a study implemented a few years ago among Saudi university students, where (47.9%) of participants reported that paracetamol has side effects, almost 87.6% of the participants failed to recognize chronic headache as a side effect of using paracetamol (Alharbi et al., 2021). Another question listed additional adverse effects of paracetamol, but only (12.4%) chose chronic headache as a possible side effect in comparison to other side effects, including fatigue and weakness (27%), stomach cramps (25%) and loss of appetite (24%) (Alharbi et al., 2021). Knowing the maximum daily dose of paracetamol was only recognized by 135 (35%) of our participants. Whether this medication overuse can cause, headache was agreed only in 54 of them (14%) among our participants. A large proportion of the university females who participated in a study at the University of Michigan did not know and could not interpret the maximum recommended daily dose from drug facts labeling (Stumpf et al., 2018). This agrees with another study done in Greece where only 12.3% of people properly answered that the maximum permitted daily dose of paracetamol was 4g (Kontogiorgis et al., 2016).

Factors affecting directly with the level of awareness in our study are age range (18-24 years), female gender, knowing whether taking paracetamol everyday can causes headache, knowing the maximum daily dose of paracetamol, awareness of paracetamol side effects, knowing that paracetamol overuse could worsen the headache and also cause chronic headache. The importance of that one should follow the physician's instructions when taking paracetamol pills. All these listed factors are statistically significantly correlated with the level of knowledge; interestingly, this knowledge was not statistically significant correlated with socioeconomic class or education. However, in one study done in Riyadh city recently confirmed that the only factor affecting the awareness about paracetamol overuse headache was educational level, where high school participants were less aware than higher education groups (Odd ratio (OR), 0.253; 95% CI, (0.07-0.916), p = (0.036)) (Alharbi et al., 2021). Self-medication of Paracetamol without prescription was identified in our sample in a large percentage 92%. This is confirmed in other studies where individuals believed it is okay to buy paracetamol from any store rather than a pharmacy.

Despite the high prevalence of MOH, it can be preventable by addressing all barriers to knowledge and implementing large educational campaigns, spreading all accessible information through programs, social media and broadcasting. It is highly recommended by Lai and his colleagues to include warning labels on packaging that may have a considerable impact on the prevention of medication overuse headache. Following education about the risk of MOH, a large proportion (80%) of participants in Lai study affirmed they would alter their analgesic taking behavior. Of these, (57%) would reduce their usage, (19%) would stop using their analgesia and (24%) would consult a physician for advice on proper headache treatment (Lai et al., 2014).

The Danish Headache Center, the Association of Danish Pharmacies and headache patient organizations implemented a four-month medication-overuse headache awareness campaign in 2016. It showed that the public knowledge level raised from 31% to 38% due to the population's education (Carlsen et al., 2018). Our study identified a poor and insufficient level of knowledge among our participants, the need to carry on a sizable metacentric cohort study to affirm knowledge gaps and the ultimate need to implement all possible educational programs among our population.

Limitation

This cross-sectional study is subject to responder bias due to the sampling technique used in the collection method and consequently we are unable to assume that the results reflect those of the general population. Some of the selected variables were estimated subjectively as it was difficult to be estimated objectively

5. CONCLUSION

Paracetamol consumption rate is evidently high in our community together with poor awareness about its role in inducing chronic headache.

Recommendations

The study highlighted the need for public mass education through implementing sizable campaigns and educational programs, in addition to the necessity for further future cross sectional research studies to provide more data about the source and magnitude of

the knowledge and to identify methods that could help to resolve all barriers and recognize all possible risk factors to be handled properly by health services.

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Informed consent

Written and oral informed consent was obtained from all individual participants included in the study. Additional informed consent was obtained from all individual participants for whom identifying information is included in this manuscript.

Ethical approval

The study was approved by the research ethics committee of Taif University with approval letter number (43-085).

Author Contributions

All authors contributed in different steps of the study.

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This study has not received any external funding.

Conflict of interest

The authors declare that there is no conflict of interests.

Data and materials availability

All data sets collected during this study are available upon reasonable request from the corresponding author.

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