

Assessment of Awareness about Paracetamol Toxicity and Paracetamol-Containing Drugs among the Public

Mohammed Al Jumaan¹, Mohye Al-Wahhas², Mona Almubayid³, Bader Alossaim², Amal Alsulibikh², Mohamed Kandil¹, Samer Al Haliq¹, Taghareed Elhoseeny⁴

¹ Department of Emergency Medical Care, Imam Abdulrahman Bin Faisal University, Dammam, 31441/1982, Saudi Arabia.

² Department of Emergency Medicine, College of Medicine, Imam Abdulrahman Bin Faisal University, Dammam, P.O. Box 1982, Saudi Arabia.

³ Johns Hopkins Aramco Healthcare, Dhahran, Saudi Arabia.

⁴ Department of Health Administration and behavioural Sciences, High Institute of Public Health, Alexandria, Egypt.

DOI: <https://doi.org/10.5281/zenodo.7656848>

Published Date: 20-February-2023

Abstract: *Background:* Paracetamol is widely used as a pain killer and antipyretic over-the-counter medications. It is usually safe; however, poisoning may happen due to lack of patient awareness of the dangers of paracetamol-containing medication leading to misuse. *Objective:* This study aimed in this study to assess the awareness about paracetamol toxicity and paracetamol-containing drugs among the public in Saudi Arabia. *Methods:* A cross-sectional study was performed during educational campaign. It included a convenience sample using a self-administered questionnaire. *Results:* Out of 432 subjects, 50.69% were male. Of these, 56.2% reported damage to the internal organs such as the liver as the most common side effect of paracetamol. A low percentage of subjects were aware of compounds, such as Relaxon, Mol, and Parafon (19.4%, 18.1%, and 17.6% respectively). Although a majority of individuals (79.2%) accepted the fact that paracetamol could be toxic, only 18.7% of them were aware of the toxic dose. The female gender, the age group of 31 to 40 years and post graduate level of education reported a significantly higher knowledge score ($p < 0.001$). *Conclusion:* We found an unsatisfactory level of awareness about paracetamol toxicity in the Eastern Province of Saudi Arabia. Moreover, several individuals failed to recognize the presence of paracetamol in many analgesics.

Keywords: Awareness, Paracetamol, Toxicity, Drugs, Acetaminophen, Over The Counter, Analgesic, Overdose, Public.

I. INTRODUCTION

Paracetamol, also known as acetaminophen, is widely used as a first-line antipyretic and analgesic, owing to its easy availability without a prescription [1]. It has proven to be effective and safe if taken in the appropriate dose; however, its misuse may result in several severe side effects [2]. During the last decade, the overall rate of suicide-related exposures involving over the counter (OTC) analgesics per 100,000 US residents grew dramatically. This trend was mostly caused by the rising exposure rate among females aged 6 to 19 years old. Paracetamol were responsible for 48.0% and 18.5% of cases, respectively, and 64.5% and 32.6% of fatalities [3]. In Saudi Arabia, Overdoses of paracetamol are regularly observed in young females making suicide attempts [4]. Furthermore, at King Abdulaziz Medical City in Saudi Arabia, a

retrospective cohort research was performed to evaluate a total of 130 instances who attempted suicide by poisoning. The majority of participants (73.8 percent, n = 96) were female. Children made up the majority of the participants (57%, n = 75). Paracetamol (59; 45.83%) and non-steroidal anti-inflammatory medicines (22; 16.92%) were the most commonly used medications. 8.5% of patients admitted to the ICU (n = 11) [5].

The clinically recommended daily dose of paracetamol should not exceed 4 g per day although the minimum dose that can cause toxicity is a single ingestion of 7.5 g [6-8]. Risk factors, such as alcoholism, smoking, and use of enzyme-inducing drugs, can result in even low doses of paracetamol to be toxic [9-11]. Inappropriate use of paracetamol can also elevate the risk of cardiovascular diseases such as stroke, heart failure, and myocardial infarction [12]. Furthermore, although rare, it may result in multiple allergic reactions, as well as hematologic and various skin disorders [13].

The most serious side effect associated with paracetamol overdose is acute liver failure (ALF). (The severity can vary to various degrees: mild, moderate, or severe, leading to encephalopathy, coagulation disorder, and renal failure [7, 14-16]. According to a study, paracetamol toxicity has emerged as the leading cause of ALF and is associated with 30% mortality [17]. Similarly, other studies have reported paracetamol overdose to cause 500 deaths per year; half of these were unintentional [18, 19].

Many people believe that drugs available in the market as OTC are safe/cannot cause any toxicities [20]. Thus, the toxicity associated with the inappropriate use of drugs such as paracetamol is largely due to a lack of awareness and misconceptions regarding the side effects of the drug. Moreover, several people never care to read the prescription on the medication labels, leading to the ignorance that several other medicines contain paracetamol as well, a situation often linked to misuse and overdose of drugs [21].

Studies assessing the level of awareness regarding paracetamol in the Eastern Province of Saudi Arabia are sparse. Considering the significant side effects of paracetamol misuse, such a study is essential. Thus, in the present study, we aimed to assess the public awareness of paracetamol toxicity and recognition of paracetamol-containing drugs in our community.

II. MATERIAL AND METHODS

Study design, setting and sample: A cross-sectional study using a self-administered questionnaire was conducted in AL Khobar, Eastern Province of Saudi Arabia in March 2019 during an educational campaign (an emergency and trauma awareness campaign). All attendants above the age of 12 years were asked to participate until the last day of the campaign. Convenience sampling was used in the selection of participants. Those who were available and willing to participate were approached and asked to fill out questionnaires. Five hundred seventy-six were surveyed, the response rate was 75% (432 participants).

Ethical considerations and data collection: This study was approved by the Institutional Review Board (IRB) of Imam Abdulrahman Bin Faisal University (Reference no.: IRB – 2019-03-173). The guidelines of Declaration of Helsinki were followed in this study. Before enrolment, potential participants, researchers explain the purpose of the study and that the participation in the study is voluntary. Furthermore, all participants were informed about the anonymity, confidentiality issue and the option of voluntary termination at any time without any repercussions on their current or future work. It was anticipated that no perceived risks were associated with the participation in this study. In addition, the researcher seek permission from the parents and the participants who were less than 18 years olds to enrolled in this study. If the participant gives his consent; then he/she will be enrolled in the study and asked to fill out the required surveys. After IRB's permission, the researcher seek permission from designated directors to conduct the study.

Measurement: At the time of consent, participants would complete a questions related to demographic data (age, gender, and level of education) to make the data interpretation and analysis easier; indications of paracetamol usage (for cold and flu, headache, vomiting, seizures, bacterial infections, help to sleep, fever); paracetamol side effects (headache, dizziness, damage to internal organs, seizure episodes, sleepiness, no side effects); paracetamol-containing drugs (Adol – Flu tab – Panadol Night – Fevadol – Tempra – Mol – Tylenol – Parafon- Relaxon – Cold & Flu); and paracetamol single toxic dose (5, 10, 15, 20, and 50 tablets). Respondents were asked to select the right answer for each question. Multiple correct answers were possible in some cases.

The questionnaire was designed on the basis of literature review and experiences of the research team [21-23]. We used the Summon search engine to search the library of the Imam Abdulrahman Bin Faisal University. A pilot survey among 20 randomly selected participants to evaluate the clarity and appropriateness of the questionnaire to Saudi Arabia culture and to determine the validity of our questionnaire.

Statistical analysis: Data were analyzed using the SPSS (Statistical Package for Social Sciences) software, version 21. Descriptive statistics were used to calculate the frequency and percentage of categorical data, whereas means and standard deviations were used for the numerical data, median and ranges were used for not normally distributed data. A knowledge score was calculated for the groups by summation of the right answers to the questions by each individual. Each right answer scored one and every wrong answer scored zero. Right answers included choosing the right indications of paracetamol (headache, high temperature, cold, and flu), side effects (damage of internal organs), medicines containing paracetamol (all the 10 medicines included), if ingesting too much paracetamol could hurt the self, and the number of tablets that caused toxicity if ingested in a single dose. Normality of the score data did not follow the normal distribution when tested using the Shapiro–Wilk test. Accordingly, non-parametric tests were used for the comparison of group means (Mann–Whitney U and Kruskal–Wallis tests). The statistical significance was set at $p \leq 0.05$.

III. RESULTS

Table 1 shows the demographic data; the study included a total of 432 participants, out of which 49.31% were female and 50.69% were male. Nearly half (48.4%) of the subjects were in the group of 21 to 30 years and 58.8% had a college level education.

Table 1: Demographic characteristics of participants.		(N = 432)	
	<i>N</i>	<i>%</i>	
Gender			
Male	219	50.69	
Female	213	49.31	
Education level			
Primary school	48	11.10	
High school	112	25.90	
College level	254	58.80	
Higher degree	18	4.20	
Age			
12 – 20 years	118	27.30	
21 – 30 years	209	48.40	
31 – 40 years	51	11.80	
41 – 50 years	24	5.60	
51 – 65 years	11	2.50	
No answer	19	4.40	

Regarding indications of paracetamol, most of the subjects (79.9%) knew that Panadol is used to treat headache; 42.1% selected high temperature and 23.4% selected cold and flu as the symptoms for which Panadol is prescribed. On the other hand, only 7% answered that Panadol had antibacterial effects, helped to go to sleep, and decreased vomiting. Adol, Panadol Night, and Fevadol were known by approximately two-thirds (68.1%, 66.7%, and 63.9% respectively) of the subjects to contain paracetamol, whereas the presence of paracetamol in Flu tablets and cold and Flu was known by approximately 40% of participants. We did not report a high percentage of individuals to be aware of the presence of paracetamol as a component of Tempra (31.5%), Relaxon (19.4%), Mol (18.1%), and Parafon (17.6%) (Table 2).

International Journal of Novel Research in Healthcare and Nursing

Vol. 10, Issue 1, pp: (92-98), Month: January - April 2023, Available at: www.noveltyjournals.com

Table 2: Participants response to indications and compounds containing paracetamol questions. (N = 432)

	N	%
Indications to use paracetamol		
Vomiting	8	1.9
*Headache	345	79.9
*High temperature	182	42.1
Help to sleep	17	3.9
Bacterial infection	5	1.2
*Cold and flu	101	23.4
Medicines containing paracetamol		
Adol	294	68.1
Fevadol	288	66.7
Panadol night	276	63.9
Flu tabs	180	41.7
Cold & Flu	177	41.0
Tempra	136	31.5
Tylenol	96	22.2
Relaxon	84	19.4
Mol	78	18.1
Parafon	76	17.6
* The correct answers.		

Public awareness of paracetamol toxicity was a concern of this study; approximately 56.2% of the subjects answered that paracetamol overuse could damage the internal organs, whereas 20.1% of the subjects reported no side effects from paracetamol overdose (Table 3).

Table 3: Participants response to paracetamol side effects questions. (N = 432)

	N	%
Side effects of paracetamol		
Sleepiness	57	13.2
Headache/Dizziness	56	13.0
Vomiting	51	11.8
Seizure episode	10	2.3
Damage of internal organ	243	56.2
No side effects over usage	87	20.1
I don't know	30	8.8

While attempting the question if one could hurt him / herself by an overdose of paracetamol, the majority of the subjects (79.2%) answered yes. On the other hand, only 18.7% of the subjects knew the correct dose, a single ingestion of which could cause harm (Table 4).

Table 4: Participants response to paracetamol toxicity questions. (N = 432)

	N	%
Can anyone ingest too much paracetamol to hurt self		
Yes	342	79.2
No	46	10.6
I don't know	44	10.2

If yes, how many tabs (500 mg for each tab) are needed to cause		
5	75	21.9
10	117	34.5
*15	64	18.7
20	43	12.5
50	13	3.8
I don't know	30	8.8
*The correct answer.		

Data in Table 5 show that females had a higher mean knowledge score than males (7.53 ± 3.46 vs. 6.21 ± 2.83) and the difference was statistically significant (Mann–Whitney U test = 18,166; $p < 0.001$). Moreover, the mean score differed significantly by age (Kruskal–Wallis test = 40.397; $p < 0.001$), with the highest mean knowledge score belonging to the age group of 31 to 40 years (8.14 ± 3.58) and the lowest score pertaining to the age group of 12 to 20 years (5.39 ± 2.88). Regarding education, those with the highest education level (master, PhD group) also had the highest mean knowledge score (9.11 ± 3.18); the mean decreased with a decline in the education level. The difference between the groups was statistically significant (Kruskal–Wallis test = 62.08; $p < 0.001$).

	Mean knowledge score	Test of significance
Gender		
Male	6.21 ± 2.83	Mann-Whitney U=18,166*
Female	7.53 ± 3.46	
Education level		
Primary school	5.29 ± 2.84	Kruskal Wallis Test=62.08*
High school	5.39 ± 2.61	
College level	7.64 ± 3.19	
Higher degree	9.11 ± 3.18	
Age		
12 – 20 years	5.39 ± 2.88	Kruskal Wallis Test=40.397*
21 – 30 years	7.37 ± 2.98	
31 – 40 years	8.14 ± 3.58	
41 – 50 years	7.54 ± 3.27	
51 – 65 years	6.09 ± 3.08	
No answer	6.47 ± 3.89	
* p<0.001		

IV. DISCUSSION

The group of volunteers participated in the present study had approximately equal number of males and females with an average age of 25 years. Moreover, since this study was part of an educational campaign, 84.7% of participants were high school and college students.

In the current study, the majority of the subjects appropriately knew the indications for the use of paracetamol, whereas only 7% of the study population had misconceptions about the real effects of paracetamol since they used it as an antibacterial or antiemetic effector and as a sleep aid. This may be due to the presence of other sedative ingredients such as antihistamine or codeine with paracetamol as combination medications.

We also found that 20.1% of the study population had the understanding that paracetamol had no side effects. This false belief of paracetamol safety might be attributed to its broad advertisement in the media, its low price, and widespread availability without prescription or any governmental regulations.

Since brands such as Panadol, Adol, and Fevadol are frequently used in our region, most participants in the study group were aware that these medications contained paracetamol. However, the majority of the participants were unaware of the presence of paracetamol in other less common drugs sold under brand names that could result in an overdose of paracetamol in case of concurrent intake.

Results of our study are similar to those of other studies in the United States [22] and United Kingdom [21] with 1,009 and 910 participants, respectively. Both studies indicated poor awareness and knowledge about paracetamol among the participants. As regard the recognition of toxic effects of paracetamol, participants in Wood's study [21] reported a better awareness (54% correct responses) compared with our study (18.7% correct responses). On the other hand, Fosnocht et al [22] reported that only 7% could identify the maximum dose. It is alarming that 16.3% of the participants believed that they could safely ingest more than 20 tablets of paracetamol.

In the current study, the degree of education was found to be significantly associated with the level of awareness regarding paracetamol; those with postgraduate qualification gained the highest level of awareness. Similarly, participants in the age range of 31 to 40 years occupied the uppermost rank which might reflect a higher grade of education and health literacy.

A study conducted by Eric et al investigated the effect of education on acetaminophen awareness. Although all participants reported poor knowledge about paracetamol, there was a significant difference between the awareness level among college educated and those in the below college group [23].

Limitations of the study: One of the limitations of the present study was that the survey was performed during an emergency educational campaign that might have led to a selection bias. In addition, 84.7% of participants were high school and college students. This could interfere with the generalization of the results.

V. CONCLUSION

The findings of the current study demonstrated that the majority of the subjects was aware of the potential toxic effects of paracetamol. However, a large proportion of them reported a lack of knowledge with regard to the toxic dose and the brand names of paracetamol-containing medicines. We believe that more strict regulations governing the trading of paracetamol and other OTC medications are required. Pharmacists need to play a more active role as an advisor to the general public. The drug labeling should clearly reveal the content of paracetamol. Furthermore, we need more educational campaigns by healthcare workers to dispel the wrong information and educate the people more about paracetamol toxicity.

REFERENCES

- [1] J. Wiliński et al., "Non-steroidal anti-inflammatory drugs and paracetamol in self-therapy of various disorders in students of different fields of study," *Folia medica Cracoviensia*, vol. 55, no. 2, p. 49, 2015.
- [2] A. Park. "The FDA's Painkiller Warning: How to Avoid Taking Too Much " *TIME USA*, LLC. <http://content.time.com/time/health/article/0,8599,1572012,00.html> (accessed September 17, 2022)
- [3] A. G. Hopkins et al., "Suicide-related over-the-counter analgesic exposures reported to United States poison control centers, 2000-2018," (in English), *Pharmacoepidemiology and drug safety*, vol. 29, no. 9, pp. 1011-1021, 2020, doi: 10.1002/pds.4997.
- [4] M. Almansori, H. Alhammadi, and F. Almulhim, "Paracetamol overdose: Analysis of a sample from a tertiary hospital in Eastern Saudi Arabia," (in English), *Saudi journal of medicine and medical sciences*, vol. 3, no. 3, pp. 209-212, 2015, doi: 10.4103/1658-631X.162000.
- [5] F. K. Alrasheed et al., "Suicide Attempts by Poisoning: An Experience From a High-Volume Emergency Department," (in eng), *Cureus*, vol. 14, no. 3, p. e23330, Mar 2022, doi: 10.7759/cureus.23330.
- [6] M. Susan E Farrell. "Acetaminophen Toxicity." <https://emedicine.medscape.com/article/820200-overview> (accessed Jan 22, 2018).

International Journal of Novel Research in Healthcare and Nursing

 Vol. 10, Issue 1, pp: (92-98), Month: January - April 2023, Available at: www.noveltyjournals.com

- [7] A. M. Larson et al., "Acetaminophen-induced acute liver failure: Results of a United States multicenter, prospective study," *Hepatology*, vol. 42, no. 6, pp. 1364-1372, 2005, doi: 10.1002/hep.20948.
- [8] I. H. Zuckerman, M. Menis, D. L. McNally, B. A. Layne, and C. D. Mullins, "Intervention for decreasing excessive acetaminophen use in Pennsylvania Medicaid recipients," *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, vol. 61, no. 22, p. 2410, 2004.
- [9] F. V. Schiødt, F. A. Rochling, D. L. Casey, and W. M. Lee, "Acetaminophen Toxicity in an Urban County Hospital," *The New England Journal of Medicine*, vol. 337, no. 16, pp. 1112-1118, 1997, doi: 10.1056/NEJM199710163371602.
- [10] A. P. 	, "The FDA's Painkiller Warning: How to Avoid Taking Too Much," in *TIME*, ed, 2006.
- [11] P. Routledge et al., "Paracetamol (Acetaminophen) Poisoning: No Need to Change Current Guidelines to Accident Departments," *BMJ: British Medical Journal*, vol. 317, no. 7173, pp. 1609-1610, 1998.
- [12] G. Glass, "Osteoarthritis," vol. 7, ed, 2005, pp. 161-179.
- [13] A. K. Rowden, J. Norvell, D. L. Eldridge, and M. A. Kirk, "Acetaminophen poisoning," vol. 26, ed. United States, 2006, pp. 49-65.
- [14] R. D. M. F. Twycross, V. F. F. Pace, M. P. C. G. P. B. R. Mihalyo, and A. D. M. F. Wilcock, "Acetaminophen (Paracetamol)," *Journal of Pain and Symptom Management*, vol. 46, no. 5, pp. 747-755, 2013, doi: 10.1016/j.jpainsymman.2013.08.001.
- [15] R. J. M. D. Fontana, "Acute Liver Failure Including Acetaminophen Overdose," *Medical Clinics of North America*, vol. 92, no. 4, pp. 761-794, 2008, doi: 10.1016/j.mcna.2008.03.005.
- [16] K. I. M. Whiteman and C. McCormick, "When your patient is in liver failure," *Nursing*, vol. 35, no. 4, pp. 58-63, 2005, doi: 10.1097/00152193-200504000-00044.
- [17] G. Ostapowicz et al., "Results of a Prospective Study of Acute Liver Failure at 17 Tertiary Care Centers in the United States," *Annals of Internal Medicine*, vol. 137, no. 12, pp. 947-954, 2002, doi: 10.7326/0003-4819-137-12-200212170-00007.
- [18] S. Kennon-McGill and M. R. McGill, "EXTRAHEPATIC TOXICITY OF ACETAMINOPHEN: CRITICAL EVALUATION OF THE EVIDENCE AND PROPOSED MECHANISMS," *Journal of clinical and translational research*, vol. 3, no. 3, 2018.
- [19] T. M. Caparrotta, D. J. Antoine, and J. W. Dear, "Are some people at increased risk of paracetamol-induced liver injury? A critical review of the literature," *European Journal of Clinical Pharmacology*, vol. 74, no. 2, pp. 147-160, 2018, doi: 10.1007/s00228-017-2356-6.
- [20] C. Panero and L. Persico, "Attitudes Toward and Use of Over-The-Counter Medications among Teenagers: Evidence from an Italian Study," *International Journal of Marketing Studies*, vol. 8, no. 3, p. 65, 2016, doi: 10.5539/ijms.v8n3p65.
- [21] D. M. Wood, E. English, S. Butt, H. Ovaska, F. Garnham, and P. I. Dargan, "Patient knowledge of the paracetamol content of over-the-counter (OTC) analgesics, cough/cold remedies and prescription medications," *Emergency medicine journal : EMJ*, vol. 27, no. 11, pp. 829-833, 2010, doi: 10.1136/emj.2009.085027.
- [22] D. Fosnocht, J. R. Taylor, and E. M. Caravati, "Emergency department patient knowledge concerning acetaminophen (paracetamol) in over-the-counter and prescription analgesics," *Emergency medicine journal : EMJ*, vol. 25, no. 4, pp. 213-216, 2008, doi: 10.1136/emj.2007.053850.
- [23] E. J. Ip, T. T. L. Tang, V. Cheng, J. Yu, and D. S. Cheongsiatmoy, "Impact of Educational Levels and Health Literacy on Community Acetaminophen Knowledge," *Journal of Pharmacy Practice*, vol. 28, no. 6, pp. 499-503, 2015, doi: 10.1177/0897190014544819.