

Understanding Unconventional Paracetamol Use in Saudi Arabia: Public Health Implications

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Abstract Paracetamol is responsible for approximately one-fourth of all medication-related toxicity. This cross-sectional study was designed to explore patient preferences for uses of paracetamol for other indications and to identify knowledge gaps among users in Saudi Arabia. The study utilized an online survey, administered through Question PRO, targeting both Saudi citizens and residents who had consumed paracetamol in the previous six months. Out of 584 participants who started the survey, 518 (88.7%) were using paracetamol at least once, with 113 (21.8%) acknowledging off-label usage, and 13.5% obtaining it without a prescription. Notably, 25% of respondents used it in combination with caffeine, codeine, and chlorpheniramine. Among those who used paracetamol off-label, nearly half n=52 (46%) were using it as a sleep aid and (21.2%) used it prophylactically to prevent illness during travel. Other than that, people also use paracetamol for calming infants and boosting energy levels. A small percentage of users mixed paracetamol with smoking devices (3.5%) or energy drinks (1.8%). The survey also revealed significant knowledge gaps among the public regarding paracetamol use. More than half (56%) of them were uncertain about the information that paracetamol and acetaminophen are the same. One quarter of the (25%) participants knew the maximum daily dose. This study highlights the prevalence of unconventional or unlicensed uses of paracetamol, as well as the substantial knowledge gaps regarding its proper use. The findings

emphasize the need for healthcare professionals to provide more comprehensive patient education on the risks associated with paracetamol, especially given its widespread availability and usage.

Keywords Paracetamol, Unlicensed Use, Off-label, Saudi Arabia, Public Health, Patient Education, Medication Toxicity

1. Introduction

Paracetamol remains to be the most popular analgesic due to its well-established safety, tolerability, and ease of availability [1,2]. Families always consider paracetamol as a first-line therapy for management of pain, which is not relieved by non-pharmacological approaches [1,2]. However, paracetamol is not devoid of toxicity. Single or repeated high doses, or after chronic ingestion of paracetamol may cause diverse toxicity symptoms [3,4]. In many countries, paracetamol comes in the upper listing of the medications implicated in overdoses. In the western world, paracetamol toxicity is one of the leading causes of acute liver failure and a global cause of morbidity [5,6]. The frequency of paracetamol overdose related to hospital admissions in Australia has increased to 44% from 2004 [6]. Similarly, in the US per year, paracetamol toxicity

leads to 56,000 emergency visits, 2,600 hospital admissions, and 500 deaths [7-9]. In 2019, 211 deaths were recorded in England due to paracetamol poisoning. Paracetamol toxicity can occur after excessive ingestion, either accidentally or deliberately [10]. Early treatment can significantly improve outcomes, making timely medical intervention crucial in cases of overdose. Knowledge gaps among consumers may be one of the factors that lead to unintended misuse and overdose. Many individuals may underestimate the importance of adhering to recommended dosages, leading to accidental overdoses. Patients' unawareness of its use includes the identification of active ingredients, confusion about the highest daily dose, and perceived safety [11-15].

Individuals use paracetamol for better sleep, even if there is no fever or pain [16,17]. Similarly, parents use it to calm the child and increase sleep [18,19]. In addition, the use of paracetamol in games, and sports enhances stamina and improves exercise length as well as reduces any pain during exercise [20-22]. Adding paracetamol into drinks including alcohol, or mixing it with Khat, or in smoking pipes has also been reported [23-25]. These behaviors highlight significant public health concerns. To avoid these risks, it is crucial to use paracetamol only as directed by healthcare professionals and to avoid altering its form of administration.

Paracetamol usage patterns have been explored by investigating OTC analgesics or paracetamol toxicity or self-medication in general [25-29]. Paracetamol exposure accounts for approximately one-fourth of all medication-related toxicity cases [29-31]. However, there exists a gap in knowledge of care givers on paracetamol use of antipyretics for fever management. To avoid these risks, it is crucial to use paracetamol only as directed by healthcare professionals and to avoid altering its form of administration. This study aims to determine the patient's preferred use of paracetamol and its factors. In addition, the study attempts to realize the knowledge gap among the paracetamol consumers for different indications.

2. Materials and Methods

Study Design

This cross-sectional study was conducted by sending an online questionnaire from January – March 2022. The study aimed to reach a diverse audience by distributing the questionnaire across various online platforms like WhatsApp, Facebook and Twitter ensuring a broad and representative sample. Participants were invited to complete the questionnaire following a brief introductory description outlining the study's objectives and significance. To accommodate a diverse population, both Arabic and English versions of the questionnaire would be made available through Question PRO. The study was approved by the Institutional Review Board, IAU

(IRB-2022-05-125).

Eligibility

Participation in the study was entirely voluntary, with each participant given the opportunity to provide informed consent before proceeding. Participants were required to read and agree to this consent form before they could access and complete the questionnaire. Eligibility of the study was limited to Saudi Arabian citizens and residents who had used paracetamol over the last six months. Participants who experienced difficulties understanding the questionnaire due to technical issues, language barriers or cognitive deficits were excluded.

Questionnaire

The questionnaire has been developed in consultation with the community and hospital pharmacists to ensure its relevance and comprehensiveness. This collaborative approach is aimed at creating a tool that accurately captures essential aspects of paracetamol use and user behavior. The questionnaire has 25 items over four sections. In the first part we collected information about the participants' backgrounds and demographics, then paracetamol prescription, and OTC use, and behavioral patterns related to paracetamol use. It included questions about the participants' typical usage patterns, such as the dosage and duration of use and preferred indications as well. The final section assessed the participants' knowledge regarding paracetamol, including its benefits, risks, and potential side effects. The questionnaire was developed in close collaboration with pharmacists who provided expertise on medication use and patient education. Their input was crucial in formulating questions that were both relevant and precise. The questionnaire underwent a validation process to ensure clarity, accuracy, and reliability. This involved pilot testing with a small group of participants and refining questions based on feedback to address any issues related to understanding or interpretation.

Statistical Analysis

Off-label use of paracetamol by the public was determined by the research team. Any use of paracetamol other than the specified indication of the specified brand or FDA indication is considered as off-label use. The data were summarized by frequencies and percentages for categorical variables and mean with standard deviation (SD) for continuous variables.

3. Results

Out of the 709 Saudi residents who were initially invited to participate in the survey, 584 individuals completed the questionnaire, resulting in a completion rate of 82.3%.

Among the participants, 357 (68.9%) were at the age of 18-49 years. A substantial majority of the participants; 432 (83.4%), were Saudi nationals. Specifically, 112 (26%) individuals were employed in various healthcare-related fields. Students comprised nearly 30% of the participants.

280 (54.0%) and one-fifth (n=106) were working in the health sector. **Table 1** provides a detailed comparison of the socio-demographic characteristics between paracetamol users and non-users.

A total of 55(10.6%) stopped the paracetamol due to unwanted side effects, however, a large majority of users, 364 (70.3%), reported being satisfied with their current use of paracetamol. This high level of satisfaction suggests that most users find paracetamol effective and satisfactory for their needs. **Table 2** presents a comprehensive overview of various aspects of paracetamol usage among the study participants.

As illustrated in **Figure 1**, approximately one-fourth of the study participants reported using paracetamol in combination with other substances such as caffeine, codeine, and chlorpheniramine.

Patients Prefer Indications of Paracetamol

Many participants (n=405, 78%) use paracetamol for its primary, label indications: as an analgesic (pain reliever) and an antipyretic (fever reducer). A smaller proportion of

users 7.55% (n=39) reported using paracetamol specifically to aid sleep. **Figure 2** provides the patient's preferred indication of paracetamol.

Patient Preferred Off Labeled/Unconventional Indications of Paracetamol

A notable percentage of participants 14.4 % (74) reported using paracetamol for various off-label indications. The top three off-label users reported were: prophylaxis to prevent sickness during travel [n=24], calming the baby (n=17) and improving the energy (n=15). Likewise, mixing paracetamol with smoking devices (3.5%) and energy drinks (1.8%) was also detected in the study population (**Figure 3**).

The Existence of Knowledge Gaps among the Labeled and Off-labeled Users

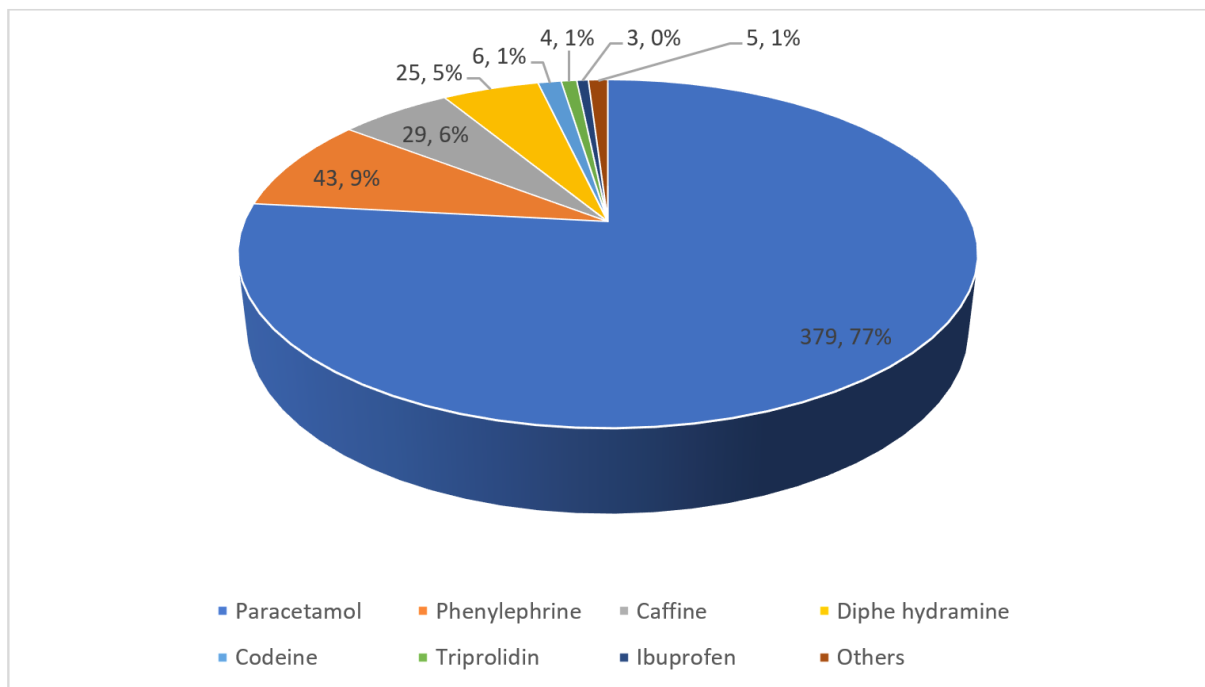
Table 3 listed the items used to measure the knowledge of paracetamol users in different groups. There is no statistically significant difference observed among the off-labeled, labeled, or only sleep indication categories. Half of the participants (56.10%) are not sure that paracetamol and acetaminophen are similar products. Three fourths of the participants agree that there exists a maximum dose of paracetamol.

Table 1. Demographic details of Paracetamol users Vs Non-users

Demographic details		Paracetamol Non-users (N=66)		Paracetamol users (N=518)	
		Count	Column N %	Count	Column N %
Age	<18 years	1	1.50%	13	2.50%
	18-40 years	51	77.30%	357	68.90%
	41-59 years	10	15.20%	126	24.30%
	>60 years	4	6.10%	22	4.20%
Gender	Male	52	78.80%	316	61.00%
	Female	14	21.20%	202	39.00%
Nationality	Saudi	60	90.90%	432	83.40%
	Non-Saudi	6	9.10%	86	16.60%
Occupation	Employed (Health Sector)	6	9.10%	106	20.50%
	Employed (Non-Health Sector)	22	33.30%	129	24.90%
	Own business	5	7.60%	23	4.40%
	Unemployed	10	15.20%	105	20.30%
	Student	23	34.80%	155	29.90%

Table 2. Paracetamol usage behaviors of participants

Paracetamol Usage behaviors		Count	Column N %
Paracetamol as OTC	Yes	448	86.50%
	No	70	13.50%
Experiencing side effects	Yes	55	10.60%
	NO	463	89.40%
Satisfaction about paracetamol use	Not satisfied	45	8.70%
	Neutral	109	21.00%
	Satisfied	364	70.30%
Read the patient information leaflet	Yes	101	21.30%
	Sometimes	193	40.70%
	No	180	38.00%

**Figure 1.** Paracetamol Combinations Preferred by Patients

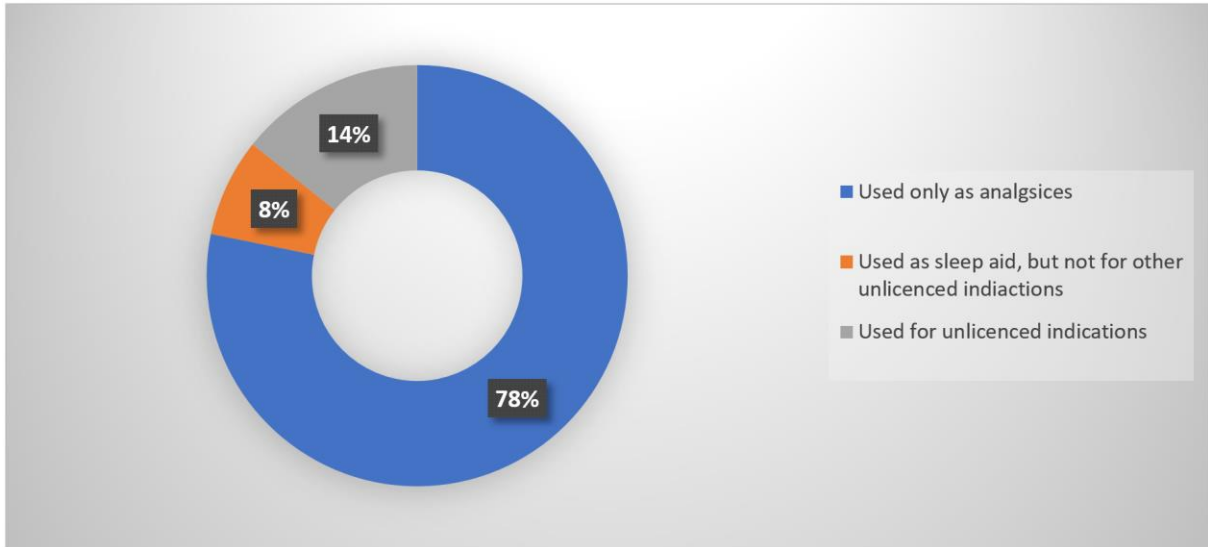


Figure 2. Patients preferred indication of paracetamol

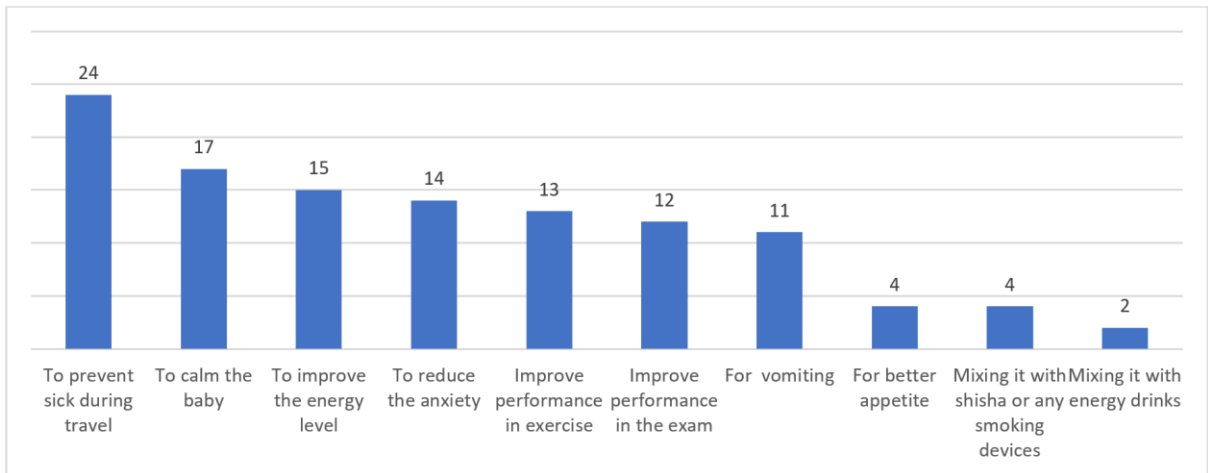


Figure 3. Patient preferred off-labeled/Unconventional indications of paracetamol

Table 3. The existence of knowledge gaps among the labeled and off-labeled users

Knowledge	Total			Labeled		Only for sleep		Off-labeled	
Paracetamol and acetaminophen are the same medication	Disagree	53	11.20%	37	10.00%	4	11.80%	12	17.40%
	Not sure	266	56.10%	211	56.90%	18	52.90%	37	53.60%
	Agree	155	32.70%	123	33.20%	12	35.30%	20	29.00%
There exists a maximum dose of paracetamol	Disagree	35	7.40%	21	5.70%	5	14.70%	9	13.00%
	Not sure	91	19.20%	75	20.20%	2	5.90%	14	20.30%
	Agree	348	73.40%	275	74.10%	27	79.40%	46	66.70%
The use of paracetamol with other medications is safe	Disagree	108	22.80%	84	22.60%	8	23.50%	16	23.20%
	Not sure	178	37.60%	137	36.90%	12	35.30%	29	42.00%
	Agree	188	39.70%	150	40.40%	14	41.20%	24	34.80%
Simultaneous use of paracetamol with other substances like alcohol is dangerous	Disagree	66	13.90%	48	12.90%	4	11.80%	14	20.30%
	Not sure	174	36.70%	146	39.40%	9	26.50%	19	27.50%
	Agree	234	49.40%	177	47.70%	21	61.80%	36	52.20%
Paracetamol use can lead to liver failure.	Disagree	49	10.30%	36	9.70%	3	8.80%	10	14.50%
	Not sure	195	41.10%	159	42.90%	9	26.50%	27	39.10%
	Agree	230	48.50%	176	47.40%	22	64.70%	32	46.40%
I take paracetamol only when I really need it and try to avoid it most times	Disagree	38	8.00%	25	6.70%	7	20.60%	6	8.70%
	Not sure	46	9.70%	30	8.10%	5	14.70%	11	15.90%
	Agree	390	82.30%	316	85.20%	22	64.70%	52	75.40%

4. Discussion

Paracetamol toxicity is well-documented in medical literature, with numerous studies identifying it as one of the leading causes of medication-related toxicity worldwide [6-9]. In fact, paracetamol consistently ranks as the most common single agent responsible for drug-induced toxicity [29]. However, the related paracetamol off-labeled or unlicensed use is a neglected area. But a diverse range of people are at threat of paracetamol misuse [30]. The present study observed different indications of paracetamol and grouped them into three main categories: The first one is labeled indications like analgesics and antipyretic, second group utilizes paracetamol only as a sleep aid. This set uses paracetamol only for enhancing sleep without any fever pain or any other comorbidity. The last group is considered as off labeled, as they use paracetamol for indications which are not listed by manufacturers or the FDA. Among the listed off labeled indications, preventing sickness during travel is the most reported indication. Studies reported that travelers frequently get ill with nausea, vomiting, and abdominal cramps. Fever was the moderately reported illness during travel [31]. The present survey was conducted during the time of Covid-19 restrictions. Several unofficial reports point out that paracetamol has been used by the passengers to get

thermal control during travel. Calming the baby is the second most reported off labeled use in our study. This is in parallel with previously published reports where they stated that many parents use paracetamol for uses other than analgesics and antipyretics which include calming down the child, facilitating sleep and rest for the whole family [18,32,33]. Another important non-medical indication reported by the public includes use of paracetamol in sports. There are several reports that paracetamol use in sports decreases pain, improves stamina and increases the exercise duration [20-22]. In addition, paracetamol is used to reduce anxiety and improve exam performance. Gisèle Pickering et al. [34] stated that paracetamol may sharpen reflection and spatial memory. Present survey: eleven participants use paracetamol for vomiting. However, a detailed history is out of scope of this study. Oya Y. Cok et al. [35] reported that intraoperative administration of intravenous paracetamol decreases the incidence of postoperative nausea and vomiting. Surprisingly few of the participants mix paracetamol with smoking devices and energy drinks. Several studies reported that paracetamol is combined with Khat to alleviate gum soreness and pain [24,25]. It has been reported that paracetamol was one of the several ingredients mixing with the head of water pipes [23]. Jordanian community pharmacists reported that paracetamol was one of the several ingredients mixing

with alcohol [25].

In the present survey, irrespective of fever and pain, 57% of respondents were using paracetamol as a sleep aid alone. Paracetamol continued to exhibit more sleep-enhancing effects in pain-free patients than placebo [16,17]. It may be due to some combination of paracetamol with diphenhydramine and codeine that can enhance sleep.

Several studies have proven that analgesics, mostly paracetamol, represent the most requested drug in the over-the-counter medication category. A similar trend was observed in the present study, where (86.07%) of the respondents admitted using it as self-medication. Irrespective of type of indication, our participants showed a lack of knowledge in different aspects of paracetamol use. Surprisingly, more than half of the participants were not sure about the fact that paracetamol and acetaminophen are the same, and 11% of them disagreed with the statement. This might lead to unintentional duplication and consequential toxicities. As demonstrated by previous studies [13-15] one-fourth (28%) of the respondents were not sure or disagreed with the statement of the maximum dose of paracetamol.

The study has a few limitations, including the use of self-administered questionnaires, which might lead to desirability bias. In addition, there may be recall bias, as in questions concerning respondents' attitudes over the six-month duration. In our study, we did not collect detailed information on the specific dosage regimens used by participants. This omission may impact the generalizability of our findings, as the variability in dosing could influence the outcomes and effectiveness of the treatment.

5. Conclusions

The survey result highlights the extent of non-medical indications of paracetamol by the public. It also demonstrates the probability of the gap existing in communities to understand appropriate use of paracetamol. Ultimately, the present study underlines the need for consistent pharmacovigilance surveillance and improving general public awareness about indications and potential dangers of paracetamol, specifically when it is used in higher than the standard doses. Additionally, the introduction of methods to assist the public in identifying paracetamol and acetaminophen in the combination formulations may prevent potential toxicities.

Conflict of Interest

None.

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