

An Evaluation on Consumers' Usage Pattern of Acetaminophen (Paracetamol): A Multicenter Study from Penang, Malaysia

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Abstract

Background: Acetaminophen poisoning is becoming an increasingly common social problem in Malaysia. An understanding of consumers' usage pattern of acetaminophen is essential in addressing the issue of accidental acetaminophen poisoning. This study was therefore aimed to evaluate the usage pattern of acetaminophen among the consumers in the state of Penang, Malaysia. **Methods:** A survey using a questionnaire was carried out in Health Clinic of University Sciences Malaysia (USM), Outpatient Clinic of Advance Medical and Dental Institute, USM, and five selected community pharmacies in the state of Penang from February 2013 to April 2013. A convenient sample of 400 Malaysian consumers was involved in this study. **Results:** Majority (98.0%) of the consumers had ever taken acetaminophen. The consumers mostly used acetaminophen for headache (75.0%) and fever (72.8%). The 500 mg acetaminophen tablet was more commonly used among the consumers (94.3%) then the 650 mg tablet (44.3%). A total of 1.1% of the consumers had taken more than two tablets of acetaminophen 500 mg tablet per intake. Meanwhile, 24.4% of the consumers had taken two tablets or more of acetaminophen 650 mg tablet per intake. The consumers mostly consumed acetaminophen in a frequency of either 4 hourly (29.5%), 8 hourly (17.3%) or 6 hourly (14.8%). However, 6.3% and 7.0% of the consumers would increase the dosage or frequency of acetaminophen consumption, respectively, when their conditions or symptoms persisted after taking the acetaminophen. **Conclusions:** The use of acetaminophen is prevalent among the surveyed consumers. The risks of acetaminophen overdose were found among the consumers.

Keywords: Acetaminophen, consumers, Malaysia, paracetamol, usage pattern

INTRODUCTION

Acetaminophen (paracetamol) is one of the most popular over-the-counter analgesic agents around the globe.^[1] Most consumers had taken acetaminophen products to treat fever,^[2-5] headache,^[6] menstrual pain,^[7] and common pain.^[8,9] A previous study in the United States showed that 78.9% of adults had used acetaminophen products in the past 6 months.^[10] Besides, a total of 94% of Australian parents found to have used acetaminophen to treat their children's fever.^[3] Efficacy, availability, affordability, and past experience were among the factors which driven the consumers to purchase acetaminophen products for self-medication.^[11]

Although the use of acetaminophen is generally considered safe, it is also the most commonly reported drugs implicated in intentional or accidental poisoning.^[12-14] A previous study in Victoria, Australia, showed that majority of the hospital admission for acetaminophen overdose were involved patients

aged between 15 and 50 years and 15% of the cases were due to accidental ingestion.^[15] Besides, acetaminophen was among the most common pharmaceutical agents involved in toxic exposures in Singapore.^[16] In United Kingdom, approximately 48% of hospital attendances related to poisoning were involved acetaminophen and it leads to 100–200 deaths annually.^[17] There were 91 deaths out of 98,578 of all acetaminophen-related poisoning cases according to data from the American Association of Poison Control Centers in 2008.^[18] Indeed, the United States Government estimated to spend US\$ 87 million every year to treat acetaminophen overdosed patients.^[19]

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In Malaysia, consumers are able to treat minor illness themselves due to easy accessibility to over-the-counter drugs including acetaminophen.^[20] However, self-medication using acetaminophen without proper information and knowledge is dangerous as this might lead to acetaminophen overdose and poisoning. Acetaminophen poisoning is becoming an increasingly common social problem in Malaysia and it involves consumers from various age groups.^[12] The poisoning requires immediate Emergency Department visits and hospital admission and this places a significant burden on healthcare costs. Indeed, the poisoning could lead to severe liver injury and even death.^[17,21,22] A previous study from overseas found that limited health literacy is the main factor which leads to inappropriate use of acetaminophen.^[23] However, currently little is known about the reasons behind the acetaminophen poisoning among the Malaysian consumers. The consumers might be unaware about the safe use of acetaminophen. An understanding of consumers' usage pattern of acetaminophen is essential to the overall planning of educational interventions to address the misuse of acetaminophen and subsequent poisoning. Therefore, this study was to evaluate the usage pattern of acetaminophen among the consumers in State of Penang, Malaysia. The research findings will help in addressing the issues around acetaminophen poisoning among the consumers in Malaysia.

METHODS

This study was conducted with a convenient sample of consumers who visited Health Clinic of University Sciences Malaysia (USM), Outpatient Clinic of Advance Medical and Dental Institute (AMDI), USM and five selected community pharmacies in state of Penang, Malaysia. The study was conducted in different locations in order to recruit the consumers from different demographic background. The sample size was calculated by using the Raosoft® software. A sample size of 400 consumers would be able to generate results with 5% margin of error and 95% confidence interval with 80% of the response distribution. An 80% of response distribution was estimated based on the working experiences of the researchers of the present study that majority of the Malaysian consumers have experiences in using acetaminophen. A sample of 152, 145, and 103 consumers was recruited from the community pharmacies, USM Health Clinic and AMDI Outpatient Clinic, respectively. Consumers above the age of 13 years old and literate in either Malay, English, or Chinese language were included in this study. Both the consumers who either have experiences in using acetaminophen product or never consumed such product were included in the study. This study excludes the healthcare practitioners and students from any medical or health field.

The study design was a cross-sectional survey which involved a questionnaire. The questionnaire was developed based on a literature review. The questionnaire consists of a section to assess the consumers' demographic characteristics, whereas the consumers' usage pattern of acetaminophen was assessed

in another section. The questionnaire was initially developed in English language and was tested for face and content validity by two experts who were academicians in the School of Pharmaceutical Sciences, USM. A forward and backward translation was performed to translate the questionnaire into Malay and Chinese language in accordance to the translation methodology.^[24] The questionnaire was further adjusted after pilot testing with five randomly selected consumers in the state of Penang.

During the data collection, the researcher (second author) approached the consumers at the study sites to seek their participation. The data were collected from February 1, 2013 to April 30, 2013. The study information sheet was then verbally explained to the potential participants and informed consent was obtained upon participant's agreement. During the data collection, the researcher referred to a laminated original questionnaire that contained questions in three different languages (English, Malay, and Chinese language). Meanwhile, consumers referred to another set of the laminated original questionnaire that contains questions in three different languages (English, Malay, and Chinese language). The researcher read out the questions according to the consumer's preferred language and the consumers reviewed the answers in the questionnaire and tell the researcher of his/her choice. Subsequently, the researcher helped the consumers to fill in nonlaminated questionnaire that contains only the English version according to the consumer's choices. The researcher explained the questions or options of the answers as well if the consumer has problems understanding the questions and answers. All responses were anonymous and confidential. Data analysis was performed by using PASW program for Windows package version 18.0 and descriptive statistic was used. This study was granted ethics approval from the USM-Hospital Lam Wah Ee Ethics Committee (ethics approval number: USM-HLWE/IEC/2012[0017]).

RESULTS

There were a total of 400 consumers who participated in the study. The demographic characteristics of the respondents are summarized in Table 1 while the usage patterns are shown in Table 2. Nearly, all of the consumers (98.0%) had ever taken acetaminophen. Retail pharmacy (63.5%), government hospital or clinic (48.5%), and sundry shop (26.8%) were among the common places where the consumers obtained their acetaminophen supply. A question was set to assess the type of acetaminophen products used by the consumers. A total of seven originator brands and one generic brand of acetaminophen products were listed as the options to choose by the respondents. The results showed that Panadol® (54.3%) and Panadol® Actifast (46.8%) were the most popular products among the respondents. Conversely, only 0.5% of the respondents consumed the generic brand of acetaminophen (Uphamol®; manufactured by CCM Pharmaceutical) [Table 1].

Table 1: Demographic and practice characteristics of surveyed consumers

Characteristics	n (%)
Location of survey	
Community pharmacies	152 (38.0)
USM health clinic	145 (36.3)
AMD I out-patients clinic	103 (25.8)
Age (years)	
13-17	16 (4.0)
18-25	159 (39.8)
26-40	132 (33.0)
41-60	71 (17.8)
61 and above	22 (5.5)
Gender	
Male	170 (42.5)
Female	230 (57.5)
Ethnicity	
Malay	191 (47.8)
Chinese	181 (45.3)
Others	28 (7.0)
Education background	
Secondary school or below	154 (38.5)
Diploma	49 (12.3)
University	197 (49.3)
Employment status	
Unemployed	50 (12.5)
Student	153 (38.3)
Employed	197 (49.3)
Marital status	
Single	214 (53.5)
Married	172 (43.0)
Divorced/widowed	14 (3.5)
Alcohol consumption	
Yes	66 (16.5)
No	334 (83.5)
Frequency of alcohol consumption (note: 1 drink equal to 250 ml beer)	
<10 drinks/week	15 (3.8)
>10 drinks/week	3 (0.8)
Occasionally	48 (12.0)
Not applicable (nonalcoholic)	334 (83.5)
Years of alcohol consumption	
<10 years	59 (14.8)
>10 years	7 (1.8)
Nonalcoholic	334 (83.5)

AMD I=Advance Medical and Dental Institute, USM=University Sciences Malaysia

Effectiveness (73.3%) was the main factor that driven the consumers to purchase the acetaminophen product. The quantities of purchase were ten tablets or less for majority of the consumers (87.3%). The consumers mostly had taken acetaminophen for headache (75.0%) and fever (72.8%), whereas few of them wrongly used acetaminophen for dizziness (0.8%). Majority of the consumers (94.3%) consumed acetaminophen 500 mg rather than 650 mg tablet (44.3%). A total of 1.1% of the consumers did not follow the proper

recommended dose of acetaminophen 500 mg tablet per intake in adults, which is should not exceeding 1000 mg (two tablets). Meanwhile, 24.4% of consumers did not follow the proper recommended dose of acetaminophen 650 mg tablet per intake in adults, which should be not exceeding 975 mg (1½ tablets). Upon the consumption of acetaminophen product, the consumers mostly consumed in a frequency of either every 4 hourly (29.5%), eight hourly (17.3%) or 6 hourly (14.8%). However, one consumer claimed that he consumed acetaminophen in every 2 h.

Approximately, three out of the five consumers would measure their body temperature with thermometer before they decide to consume acetaminophen for fever. Nevertheless, only 13.0% of consumers had consumed acetaminophen when their body temperatures were between 38.5°C and 39°C. A total of 44.1% of the respondents consumed acetaminophen under a lower body temperature (38°C or less). The respondents reported various behaviors when their conditions or symptoms persisted after taking acetaminophen. Apart from consulting their healthcare professionals (66.5%), 6.3% and 7.0% of them would increase the dosage or frequency of acetaminophen consumption, respectively. However, a few respondents (18.0%) would ignore the persistent conditions or symptoms. About 92.0% of consumers reported that they would keep acetaminophen at home and 75.0% of them would bring it along while travelling.

More than half of the consumers (62.5%) would read the instructions on the package before consuming acetaminophen. However, 1.8% and 5.0% among these consumers do not understand and follow the instructions, respectively. Approximately, 64% of consumers reported that medical advices were given to them when purchasing the acetaminophen containing products. The majority of the respondents received medical advices of acetaminophen from pharmacist (46.5%) and doctor (31.5%). Meanwhile, a few consumers reported getting information about acetaminophen from their friends (7.3%) and families (0.3%). Only 5.8% of the consumers did not follow the medical advices regarding acetaminophen use. When looking at the types of medical advices received by the consumers, information about the dosage (40.0%), frequency (27.5%), and indication (26.3%) were most commonly given to them. Considering the consumers who prescribed with warfarin ($n = 18$), only one consumer did received medical advices regarding interaction between these two drugs [Table 2].

DISCUSSION

This study showed that the prevalence of acetaminophen used among the surveyed consumers was high. The consumers found to be more familiar with originator brand of acetaminophen products. Besides, the 500 mg acetaminophen tablet was more commonly used among the consumers as compared to 650 mg tablet. The reasons to consume acetaminophen among the consumers resemble those found in international studies, for

Table 2: Consumers' usage pattern of acetaminophen (paracetamol)

Question number	Survey questions	n (%)
1	Have you ever taken paracetamol?	
	Yes	392 (98.0)
	No	8 (2.0)
2	Where do you obtain paracetamol? (you can choose more than one answer)	
	Supermarket	69 (17.3)
	Pharmacy	254 (63.5)
	Sundry shop	107 (26.8)
	Government hospital or clinic	194 (48.5)
	Chinese medicine shop	2 (0.5)
	Pharmaceutical industry	5 (1.3)
3	What type of paracetamol you use? (you may choose more than one answer)	
	Panadol®	217 (54.3)
	Panadol® Soluble	138 (34.5)
	Panadol® Actifast	187 (46.8)
	Panadol® Muscle relief	31 (7.8)
	Panadol® Menstrual	27 (6.8)
	Panadol® Cold	10 (2.5)
	Panadol® Cold and Flu	53 (13.3)
	Uphamol®	2 (0.5)
4	What is the main factor that you consider when purchase the paracetamol?	
	Effectiveness	293 (73.3)
	Dosage form design	9 (2.3)
	Quality	52 (13.0)
	Quantity	3 (0.8)
	Cost	35 (8.8)
	Not applicable	8 (2.0)
5	Normally, what is the quantity of your purchase?	
	≤10 tablets	349 (87.3)
	11-30 tablets	36 (9.0)
	31-50 tablets	6 (1.5)
	≥100 tablets	1 (0.3)
	Not applicable	8 (2.0)
6	Under what conditions do you use paracetamol? (you may choose more than one answer)	
	Headache	300 (75.0)
	Backache	34 (8.5)
	Toothache	31 (7.8)
	Menstrual pain	42 (10.5)
	Fever	291 (72.8)
	Cold	36 (9.0)
	Flu	99 (24.8)
	Dizziness	3 (0.8)
7	What is the dosage for the tablets that you take? (you may choose more than one answer)	
	500 (mg)	377 (94.3)
	650 (mg)	177 (44.3)

*Contd...***Table 2: Contd...**

Question number	Survey questions	n (%)
8	How many tablets of paracetamol (500 mg/tablet) do you take each time?	
	1 tablet	116 (29.0)
	2 tablets	257 (64.3)
	3 tablets	2 (0.5)
	4 tablets	1 (0.3)
	>5 tablets	1 (0.3)
	Not applicable	23 (5.8)
9	How many tablets of paracetamol (650 mg/tablet) do you take each time?	
	1 tablet	80 (20.0)
	2 tablets	95 (23.8)
	3 tablets	1 (0.3)
	4 tablets	1 (0.3)
	>5 tablets	0 (0.0)
	Not applicable	223 (55.8)
10	Do you use paracetamol syrup/suppository to treat your children?	
	Yes	103 (25.8)
	No	289 (72.3)
	Not applicable	8 (2.0)
11	How often do you use paracetamol tablet/syrup/suppository?	
	Every month	12 (3.0)
	Every week	5 (1.3)
	Everyday	1 (0.3)
	Whenever the condition appears	367 (91.8)
	Not applicable	8 (2.0)
	Missing data	7 (1.8)
12	Upon your consumption of paracetamol tablet/syrup/suppository, how frequent do you take it?	
	Every 2 h	1 (0.3)
	Every 4 h	118 (29.5)
	Every 6 h	59 (14.8)
	Every 8 h	69 (17.3)
	>8 h	145 (36.3)
	Not applicable	8 (2.0)
13	Do you take paracetamol tablet/syrup before or after meal?	
	Before meals	26 (6.5)
	After meal	366 (91.5)
	Not applicable	8 (2.0)
14	If your conditions or symptoms persist after taking paracetamol, what would you do?	
	Double the dose	25 (6.3)
	Take it more frequently	28 (7.0)
	Consult a doctor/pharmacist	266 (66.5)
	Ignore the conditions/symptoms	72 (18.0)
	Others	1 (0.3)
	Not applicable	8 (2.0)
15	Do you measure body temperature with thermometer before you decide to consume paracetamol?	

Contd...

Table 2: Contd...		
Question number	Survey questions	n (%)
16	Yes	237 (59.3)
	No	155 (38.8)
	Not applicable	8 (2.0)
	When fever occurs, in what body temperature will cause you to consume paracetamol?	
	36.5°C-37.0°C	61 (15.3)
	37.5°C-38.0°C	115 (28.8)
	38.5°C-39.0°C	52 (13.0)
	>40.0°C	9 (2.3)
	I don't know	155 (38.8)
17	Not applicable	8 (2.0)
	Do you bring paracetamol along while travelling?	
	Yes	300 (75.0)
18	No	92 (23.0)
	Not applicable	8 (2.0)
	Do you keep paracetamol in your house?	
19	Yes	368 (92.0)
	No	24 (6.0)
	Not applicable	8 (2.0)
20	Do you read the instructions of the package before you consume paracetamol?	
	Yes	250 (62.5)
	No	142 (35.5)
21	Not applicable	8 (2.0)
	Do you understand the instruction?	
	Yes	243 (60.8)
22	No	7 (1.8)
	Not applicable	150 (37.5)
	Do you follow the instructions on the package?	
23	Yes	230 (57.5)
	No	20 (5.0)
	Not applicable	150 (37.5)
24	Do you receive any medical advice regarding paracetamol consumption when you purchase it?	
	Yes	257 (64.3)
	No	134 (33.5)
	Not applicable	8 (2.0)
	Missing data	1 (0.3)
	From whom do you receive the information? (you may choose more than one answer)	
	Doctor	126 (31.5)
	Pharmacist	186 (46.5)
	Nurses	43 (10.8)
Friends	29 (7.3)	
Internet	9 (2.3)	
Advertisement	31 (7.8)	
Family	1 (0.3)	

Contd...

Table 2: Contd...		
Question number	Survey questions	n (%)
24	Do you follow the medical advice regarding paracetamol consumption?	
	Yes	234 (58.5)
	No	23 (5.8)
25	Not applicable	143 (35.8)
	What kind of medical advice do you receive? (you may choose more than one answer)	
	About what the conditions is used for	105 (26.3)
	About how much should I take	160 (40.0)
	About how frequent should I take	110 (27.5)
	About the side effects	39 (9.8)
	Under what conditions I can't consume paracetamol	31 (7.8)
	Others	2 (0.5)
	Are you taking warfarin?	
26	Yes	18 (4.5)
	No	382 (95.5)
27	Do you take paracetamol with warfarin?	
	Yes	10 (2.5)
	No	8 (2.0)
28	Not applicable	382 (95.5)
	Did anyone give you any medical advice regarding paracetamol with warfarin, which can increase risk of bleeding, especially with the dosage of paracetamol more than 325 (mg/day), (long-term effect)?	
	Yes	1 (0.3)
	No	17 (4.3)
	Not applicable	382 (95.5)

instance, to treat fever,^[2-5] headache,^[6] and common pain.^[8,9] However, a small number of consumers noted to have misused acetaminophen for the treatment of dizziness. The consumers need to be educated on the proper indication of acetaminophen as the misuse of nonprescription medicines for self-medication could potentially causes delay in treating severe medical conditions.^[20]

Acetaminophen can cause poisoning if the user exceeded the recommended dose.^[1,14,22,25] The recommended dosage for children is 15 mg/kg every 4–6 h, up to a total of 2400 mg a day. Whereas, the recommended dosage for adult is 500 mg to 1000 mg every 4–6 h, up to total daily dose of 4000 mg.^[26] An acute single ingestion of acetaminophen dose >10 g or 200 mg/kg (whichever is lower) in adult or 200 mg/kg in children will lead to liver toxicity.^[22] In addition, repeated supra-therapeutic doses ingestion of acetaminophen over a period of more than 8 h can leads to acetaminophen poisoning as well.^[14,25] Indeed, previous reported data revealed that the patients with repeated suprathreshold ingestion of acetaminophen have higher mortality rate than those with single time point overdose.^[14] The present study found some

worrying usage patterns among the consumers, which might place them at risk of acetaminophen poisoning. A total of 1.1% and 24.4%, respectively, of the respondents found to have exceeded the recommended dosage per intake for 500 mg and 650 mg tablet. In addition, 6.3% and 7.0% of the consumers would increase the dosage or frequency of acetaminophen consumption, respectively, when their conditions or symptoms persisted after taking acetaminophen. There was a possibility that the consumers were not aware of the maximum daily dose of acetaminophen and subsequently may leads to the overconsumption of acetaminophen. A previous study by Hornsby *et al.* conducted among 284 adults in the United States showed that 10% of respondents viewed maximum dose of acetaminophen as >4 g and 25% were unsure of the maximum dose.^[27]

Acetaminophen is generally not recommended to use for asymptomatic mild fever with body temperature <38.5°C.^[26] As the immunological benefits of fever are decreased at body temperature of 40.0°C, the use of acetaminophen is needed only when the body temperature is approaching moderate fever of 40.0°C.^[28,29] In fact, previous studies showed that many children can tolerate low-grade fever up to 39.0°C and body temperature reduction with antipyretic is not always necessary.^[28,29] Nevertheless, in the present study, around 40% of the consumers did not measured their body temperature before the used of acetaminophen. Among the consumers who measured their body temperature prior to acetaminophen consumption, a high proportion of them consumed acetaminophen although they were having low-grade fever. These findings suggested the need of education intervention to alert the consumers about the proper indication for acetaminophen in the treatment of fever.

Approximately, one-third of the respondents did not receive any medical advice regarding acetaminophen consumption. In addition, among those who received medical advice, <10% of them have been informed about the side effects and conditions in which acetaminophen should not be used. As 5.5% of the respondents were aged above 60 years, they might have chronic illnesses treated with prescription medicines. The present study noted that slightly more than half (55.5%) of the consumers who prescribed with warfarin found to have consumed warfarin together with acetaminophen and majority of them did not receive advice regarding interaction between these two medicines. An interview conducted in Estonia revealed that the concurrent use of prescription medicine and over-the-counter medicine was common among the elderly and this might expose them to clinically significant drug-drug interaction.^[30] A survey in North Carolina involved 39 elderly adults found greater utilization of over-the-counter medicines among older adults with more chronic illnesses.^[31] The above findings highlighted the strong need for healthcare provider to screen for possible drug-drug interaction whenever an elderly adult is purchasing acetaminophen. Besides, the consumers need to be educated on the interaction between acetaminophen and alcohol as well. A proportion of the consumers in the

present study was chronic alcohol users, and they need to be alerted about the safety concerns in simultaneous use of acetaminophen and alcohol. Previous reports showed that chronic alcoholics are at risk of serious liver toxicity when taking acetaminophen even in therapeutic doses.^[32]

There were some limitations in this study. The present study only recruited the consumers from the state of Penang. Besides, the recruitment of the consumers in this study did not involve those from sundry shop, shopping mall, or supermarket where the consumers may have different acetaminophen usage pattern. Hence, the generalizability of the findings is somewhat limited. In addition, the used of convenient sampling in the study might possible led to selection bias. Therefore, this study is valuable in providing a suggestive baseline data on Malaysian consumers' usage pattern of acetaminophen. A nationwide study involve multicenter and random sampling would overcome the limitation of the present study.

CONCLUSIONS

The use of acetaminophen is prevalent among the surveyed consumers. The consumers found to have lack of medical advice regarding the proper dosage, side effects of acetaminophen, and interactions with other agents. The risk of acetaminophen overdose existed among the consumers. All these issues need to be addressed promptly in order to avoid acetaminophen poisoning among the consumers.

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Conflicts of interest

There are no conflicts of interest.

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