



Knowledge and Practice of Caregivers Towards Paracetamol Administration in Children – A Cross - sectional study

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Abstract

Introduction: Paracetamol is an effective anti-pyretic and analgesic when taken in prescribed appropriate dose, whereas overdosing of the same may cause serious morbidity and mortality. This study was done to assess the knowledge and practice of caregivers towards paracetamol administration in children.

Methods: A cross-sectional study was done among 255 caregivers accompanying the children up to the age of 12 years. A predesigned questionnaire was used to collect the socio-demographic variables and for assessing the knowledge and practice. The Statistical Package for Social Sciences (SPSS, version 22.0) was used for statistical analysis.

Results: Significant association was noted between age and socioeconomic class and knowledge of giving paracetamol without doctor's advice with the level of paracetamol dosing. The practice of using measuring cups for giving paracetamol suspension or the specific dosage proportion for paracetamol tablet were statistically significant with the level of paracetamol dosing.

Conclusions: The knowledge and act of caregivers towards paracetamol administration is significantly associated with age, socioeconomic class, using measuring cups and dosage proportion for paracetamol tablet.

Introduction

Paracetamol is an easily available over the counter drug and widely used analgesic and antipyretic in children. Although the drug has a good safety profile in its therapeutic range, it is quite alarming to see that paracetamol toxicity is the second most common cause of liver transplantation globally.¹ In the United States acetaminophen toxicity has led to 56,000 emergency department visits, 2,600 hospitalizations and 500 deaths per year.¹ In a retrospective research from south India, among 125 children with acute liver failure between one month to 18 years children, paracetamol toxicity contributed to 21%.²

Paracetamol overdosing are usually asymptomatic or may develop mild symptoms like nausea and vomiting in the first 24 hours. This can go easily unnoticed or ignored either by parents or caregivers. This may be putting the children at the risk of delaying the treatment, hence worsening the outcome.

As it is over the counter drug and mostly used by parents at home, the chances of overdosing and poisoning is quite high. In India, the research on paracetamol poisoning is relatively less. Hence, this study was carried out with the main aim of assessing the knowledge and practice of caregivers towards paracetamol

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administration in children.

Methods

This was a cross-sectional study done over a period of three months in the Department of Paediatrics, Sree Balaji Medical College and Hospital, Chennai, Tamil Nadu, India from April 2021 to June 2021. The study was initiated after obtaining ethical clearance from the Institutional Ethics Committee. All consenting caregivers accompanying children up to the age of 12 years who had fever within past one month were enrolled. They were asked to respond to the predesigned questionnaire which was typed in two languages English and Tamil. Volunteers helped to fill up the questionnaire for caregivers who were illiterate and who had difficulty in recording the responses. Caregivers who did not consent, those who are not the usual person to give paracetamol, to whom no antipyretic drug was administered and to whom antipyretics other than paracetamol were administered were excluded. The sample size was calculated as 240. This was calculated using Nithisha T et al with an estimated knowledge on consequences of paracetamol overdose (P) = 19.3% with absolute precision of 5% and 95% confidence interval (CI). Convenience sampling was used, and questionnaire was distributed to randomly selected 255 caregivers. The questionnaire had three sections.^{3,4} Section 1 included information regarding the socio demographic variables. The socioeconomic status of the participants was classified according to the modified BG prasad scale 2022, which included five classes namely class I (upper class) with per capita income \geq Rs. 8397, class II (upper middle class) with per capita income Rs. 4156 - 8396, class III (middle class) with per capita income Rs. 2460 - 4155, class IV (lower middle class) with per capita income Rs. 1272 - 2456, class V with per capita income less than Rs.1272.⁵ Section 2 included the weight of the child in kilograms. Dose of the paracetamol given to the child was calculated in mg / kg / dose. Section 3

had two parts – A and B. Part A had the following questions on knowledge of the caregivers, “Do you think paracetamol can be given to children (as self-medication) without doctor’s advice? Do you think paracetamol is a harmless drug? Do you know the complications of paracetamol overdosing?” and the responses from the participants were recorded as ‘yes’ or ‘no’. Part B had the following questions on practice of caregivers, “Do you always get doctor’s advice before giving paracetamol?, Do you give paracetamol on advice from pharmacist or friends or relatives?, Do you always use either a measuring cup for giving paracetamol suspension or specific dosage proportion for giving paracetamol tablet?” The questionnaire was validated by conducting a pilot study which included 30 participants who were not included in the main study. Face validity was done by giving the questionnaire to five mothers and the content was checked by the experts in our Department and University. Association between demographic variables and knowledge and practice were analysed using Chi-square test. The p-value of < 0.05 was considered statistically significant. Odds ratio was given with 95% confidence interval. Statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS, version 22.0).

Results

The demographic variables of the participants are shown in Table 1. Although most of the children were in the age group of 0 - 4 years (50.20%), overdosing (> 15 mg / kg / dose) was seen more in the age group of 9 - 12 years (31.25%) {P value of 0.02 and odds ratio (OR) of 2.09 with 95% confidence interval 1.00 to 4.36}. The association between the socioeconomic class and the level of paracetamol dose was also statistically significant ($P = 0.001$). The gender, age and education of the caregiver, relationship to the child, residence with the level of paracetamol were not significant.

Table 1 : Association between demographic variables and paracetamol dose

Demographic variables		Dose				N	Chi square test	Odds Ratio (95% CI)
		≤ 15 mg / kg / dose		> 15 mg / kg / dose				
		N	%	N	%			
Age	0 - 4 years	110	85.93%	18	14.07%	128	$\chi^2 = 8.80$ P = 0.02*	2.09 (1.00 - 4.36)
	5 - 8 years	69	87.34%	10	12.66%			
	9 - 12 years	33	68.75%	15	31.25%			
Sex	Male	123	84.83%	22	15.17%	145	$\chi^2 = 0.69$ P = 0.41	1.31 (0.68 - 2.54)
	Female	89	80.91%	21	19.09%	110		
Age of caregiver	20 - 35 years	164	84.54%	30	15.46%	194	$\chi^2 = 3.64$ P = 0.16	1.48 (0.71 - 3.06)
	36 - 50 years	46	80.70%	11	19.30%	57		
	51 - 65 years	2	50.00%	2	50.00%	4		
Relationship to child Mo / Fa / Gp / R / O	Father (Fa)	52	82.54%	11	17.46%	63	$\chi^2 = 1.25$ P = 0.54	0.95 (0.44 - 2.01)
	Mother (Mo)	156	83.87%	30	16.13%	186		
	Grandparents (Gp)	4	66.67%	2	33.33%	6		
Education of caregiver I / S / D	Illiterate (I)	11	73.33%	4	26.67%	15	$\chi^2 = 2.50$ P = 0.29	0.59 (0.27 - 1.29)
	School (S)	135	81.82%	30	18.18%	165		
	Degree (D)	66	88.00%	9	12.00%	75		
Socioeconomic class (BG prasad scale 2022)	Upper class	54	96.43%	2	3.57%	56	$\chi^2 = 10.95$ P = 0.001*	3.39 (1.53 - 7.49)
	Upper middle class	94	82.46%	20	17.54%	114		
	Middle class	53	74.65%	18	25.35%	71		
	Lower middle class	11	78.57%	3	21.43%	14		
Residence R/U	Rural (R)	43	78.18%	12	21.82%	55	$\chi^2 = 1.23$ P = 0.27	0.67 (0.32 - 1.42)
	Urban (U)	169	84.50%	31	15.50%	200		

*Statistically significant

The amount of paracetamol given to the children based on their weight are summarised in Table 2.

Table 2: Dosage of Paracetamol given to the children based on weight

Dose of paracetamol given		
mg / kg / dose	N	Percent %
< 10 mg / kg / dose	34	13.3
11 - 15 mg / kg / dose	178	69.8
16 - 20 mg / kg / dose	34	13.3
> 20 mg / kg / dose	9	3.5
Total	255	100

Although 72.55% (N = 185) of participants had knowledge that paracetamol should not be given without doctor's advice,

27.45% (N = 70) accepted that paracetamol can be given without doctor's advice and this was statistically significant with p value of 0.02. This knowledge on paracetamol administration has a high risk of association with the drug overdose in children with the odds ratio (95% confidence interval) of 2.21 (1.12 - 4.38). Table 3 summarises the results of the knowledge of caregivers towards paracetamol administration in children.

Table 3: Knowledge of caregivers towards paracetamol administration

Knowledge		Dose				n	Chi square test	OR (95%CI)
		< 15 mg / kg		> 15 mg / kg				
		n	%	n	%			
K1) Do you think paracetamol can be given to children without doctor's advice?	Yes	52	74.28%	18	25.72%	70	$\chi^2 = 5.39$ P = 0.02*	2.21 (1.12 - 4.38)
	No	160	86.49%	25	13.51%	185		
K2) Do you think paracetamol is a harmless drug?	Yes	49	80.33%	12	19.67%	61	$\chi^2 = 0.45$ P = 0.43	0.78 (0.37 - 1.62)
	No	163	84.02%	31	15.98%	194		
K3) Do you know the complications of paracetamol overdosing?	Yes	35	85.37%	6	14.63%	41	$\chi^2 = 0.17$ P = 0.68	1.21 (0.47 - 3.10)
	No	177	82.71%	37	17.29%	214		

*Statistically significant

Majority of the participants (71.37%) (N = 182) in our study had a practice of getting doctor's advice before giving paracetamol to children and only 10.2% (N = 26) gave paracetamol to children on advice from pharmacist, friends, or relatives. Both practices of caregivers towards paracetamol administration to children were not statistically significant.

Discussion

Paracetamol is an easily available antipyretic analgesic over the counter medication. It is a safe drug when it is taken in appropriate dose and frequency. When the dosage exceeds the recommendation, it can result in serious side effects like gastrointestinal bleeding, hepatic and renal injury.⁶ Recent concerns have also been raised about the association of paracetamol drug with bronchoconstriction, lung injury and development of asthma in children.^{7,8}

Table 4: Practice of caregivers towards paracetamol administration

Practice (P)		Dose				n	Chi square test	OR (95% CI)
		< 15 mg / kg		> 15 mg / kg				
		n	%	n	%			
P1) Do you always get doctor's advice before giving paracetamol?	Yes	151	82.97%	31	17.03%	182	$\chi^2 = 0.01$ P = 0.91	0.96 (0.46 - 1.98)
	No	61	83.56%	12	16.44%	73		
P2) Do you give paracetamol on advice from pharmacist or friends or relatives?	Yes	21	80.77%	5	19.23%	26	$\chi^2 = 0.11$ P = 0.73	0.83 (0.29 - 2.35)
	No	191	83.41%	38	16.59%	229		
P3) Do you always use measuring cups for giving paracetamol suspension or specific dosage proportion for paracetamol tablet?	Yes	203	84.58%	37	15.42%	240	$\chi^2 = 6.08$ P = 0.01*	3.65 (1.22 - 10.88)
	No	9	60.00%	6	40.00%	15		

*Statistically significant

Majority of the participants 94.12% (N = 240) were either using measuring cups or specific proportion of the tablet to administer paracetamol to the children and 5.88% were not following that (P = 0.01). The odds ratio with 95% confidence interval was 3.65 (1.22 - 10.88). Table 4 summarises the results discussed above.

In UK, the proportion of the overdoses with paracetamol increased from 14.3% in 1976 to 42% in 1990, and in 1993, 47.8% of all the overdoses which were reported, involved paracetamol or paracetamol-containing drugs.⁹ In the present study 13.3% of caregivers gave paracetamol in the dose of 16 - 20 mg / kg / dose and 3.5% gave the dose exceeding 20 mg / kg / dose. In a study done by Ramanayake et al in 2012, 43% have given the paracetamol greater than 15 mg

KAP towards paracetamol administration

caregivers shows a decreasing trend, a retrospective study done in a tertiary paediatric critical care in south India reported that paracetamol toxicity has contributed to 21% of the total paediatric acute liver failure.² This data is quite alarming and can be prevented if efforts are taken to educate the community regarding the hazards of self-medication of paracetamol.

The study by Ramanayake et al also noted that children above three years of age were at higher risk of getting the incorrect dose of paracetamol.⁴ But in the present study overdosing (> 15 mg / kg / dose) was seen in the older children between nine to 12 years rather than younger children. This may be due to the fact that as the children grow older caregivers have a tendency to give them the adult dosage of medicines, which indirectly reflects their ignorance. This also hints that caregivers are more vigilant and take utmost care in drug administration when the children are young. As the age advances, the fear of overdosing comes down for the caregivers. It is very essential to create awareness to the caregivers that children entering the adolescent age group also needs doctor's advice and early adolescents are not equivalent to adults, henceforth utmost care should be taken when giving medicines for them.

The only socio demographic variable which was significant in the present study was socio economic status. The overdosing was seen more in middle class which may be attributed to the ignorance and unawareness prevailing in the community.

Parents and caregivers often consider fever as a dangerous symptom of infection and correlate the severity of the illness with the grades of temperature. This fever phobia among the caregivers leads to the inappropriate administration of the paracetamol drug, making them vulnerable to the dreadful adverse effects of the drug. In the present study most participants (72%) had a knowledge that paracetamol should not be given without doctor's advice, and this had a significant association with the paracetamol overdose whereas in a similar study done by Nithisha T et al only 15% stated the same.³ In the present study the awareness about complications of overdosing was known to 16% of the caregivers which was similar to the study by Nithisha T et al (19.3%), whereas 26% knew the harmful effects of paracetamol overdosing in the study done by Ramanayake et al in 2012.^{3,4} Despite more than two thirds of the participant being not aware of the complications of paracetamol overdosing, this association of the knowledge with overdosing was not statistically significant.

The present study noted that 71% had a practice of administering paracetamol to children after getting doctor's advice and paracetamol overdose was seen in 17.03% of those who had the attitude of following the doctor's prescription. In a Sri Lankan study done by Ramanayake et al, 45.2% had overdose of paracetamol which is more than seen in the present study.⁴ This result highlights the fact that physician's knowledge on dosing and frequency of the drugs

is very important irrespective of specialization of medical field. There may be a possibility of following the wrong dosing despite the correct prescription by the physician due to the ignorance, misunderstanding, improper communication, illiteracy, forgetfulness, or carelessness of the caregivers. Future research work is needed to conclude possible causable factors.

In a study done in Nigeria by Obu et al it was reported that 45% self-administered paracetamol, 6.5% of the participants administered paracetamol on advice from nurse and 4.3% from pharmacist.¹⁰ In the present study most of the subjects denied giving paracetamol on advice from pharmacist or relatives or friends. 92.16% of the participants gave paracetamol after getting doctor's prescription, 6.67% had the practice of getting advice from the pharmacist and 1.16% gave paracetamol after getting relatives advice. These changes in the practice of the participants are an appreciative outcome when compared to the previous study.

In the present study 18% gave tablet formulation to the children and the rest used either syrup (74.50%) or drops (7.45%). In Nithisha T et al's study, only 2% have used the tablet form and the rest of the participants used syrup or drops.³ Irrespective of the different forms (drop / syrup / tablet / suppository) being used, caregivers should be aware of the fact that dosage specifications vary as the concentration of the drug differs in each form. As paracetamol is an easily available over the counter medication it may be quite useful for the community if there are information regarding weight appropriate dosages are printed on the bottles and tablet covers.

The practice of using standard measuring cups for administration of paracetamol suspension and specific dosage proportions in case of tablet forms are very important and this association was statistically significant in the present study. This practice may look simple but when followed correctly, it prevents and reduces mortality and morbidity associated with paracetamol poisoning. In the study by Ramanayake et al, the knowledge about various measuring devices like standard cups, teaspoon, dropper used by the participants were assessed.⁴

This study emphasises the importance of the knowledge of caregivers about the detrimental effects of self-prescription, without the physician's advice and the importance of using measuring cups to medicate the children both of which were statistically significant. It is also critically important for the physicians and paediatricians to clearly specify the formulation, dosage, dosing frequency and duration of use.

The present study was conducted in a single tertiary care hospital and being a cross sectional study, it could predict only the association but not the causality. Despite the limitations of the study, the results may bring awareness to the public and henceforth prevents the untoward complications of the most easily available over the counter drug paracetamol in children.

Conclusion

This study emphasises the importance of the knowledge of caregivers about the detrimental effects of self-prescription, without the physician's advice and the importance of using measuring cups to medicate the children both of which were statistically significant in our study.

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