PRE-HOSPITAL USE OF PARACETAMOL IN THE RIVERS STATEUNIVERSITY TEACHING HOSPITAL PAEDIATRIC OUTPATIENT CLINIC

ABSTRACT

Background

Paracetamol is a medication that is often procured over the counter in many nations including Nigeria. It is therefore prone to abuse/misuse with consequences.

Objective of the study

To determine the prevalence of pre-hospital use of paracetamol, preferred formulation, appropriateness of dosing and factors associated with its use.

Methodology

An observational study involving 401 caregiver/child pair seen at the Paediatric clinic of the RSUTH over 6months. Data on demography, clinical symptoms, weight of the children as well as pre-hospital paracetamol use were obtained using a semi-structrured questionnaire. Informed consent was obtained from the caregivers.

Results

A total of 401 caregivers/child pairs participated in the research with male predominance. The average age of the children was 28.26 ± 3.80months. Most of the parents were aged 30-40 years, traders/businessmen with tertiary level of education. About 40% of children received paracetamol before presentation at the hospital with fever being the commonest reason. Syrup was the preferred formulation while 0.6% received injection paracetamol. Commonest reason for formulation type was the age

of the child followed by available paracetamol formulation at home. Most parents gave paracetamol twice daily, for less than seven days and based on past experiences. The commonest diagnosis among parents that gave paracetamol was malaria. A quarter of children received underdose and 5.4% overdose medication.

Conclusion

Pre-hospital paracetamol self-medication is common with syrup paracetamol being the commonest formulation used. There was a high abuse of paracetamol thus education of the populace on appropriate pre-hospital paracetamol use would help reduce this menace.

Keywords: Abuse, Paracetamol, Pre-hospital, Self-medication

Introduction

Paracetamol, also known as acetaminophen is a pharmaceutical drug, an analgesic and antipyretic used commonly by adults and children. It is one of the over-the-counter (OTC) drugs sold in pharmacies, supermarkets and other stores thus may not require a doctor's prescription before its' purchase and use. Little wonder, it is commonly administered to children by parents and caregivers at home before presentation at the hospital. It has been in use for more than 70 years and eases mild to moderate pain as well as lowers high temperatures about 30 minutes after a dose has been taken. [1] It is worthy of note that its' effect usually last for about 4-6 hours. [1]

The analgesic and antipyretic effects of paracetamol occur through the inhibition of prostaglandin production centrally. [2] Paracetamol however has very little anti-inflammatory effect as seen in non-steroidal anti-inflammatory drugs. [2] An observational prospective study carried out in Enugu, [3] South east Nigeria

documented the commonest reason for paracetamol administration to children among mothers/caregivers being fever (68.4%) while other reasons were cough and/or cattarrh (7.4%), abdominal pain (3.9%) and earache (3.5%). Similarly, Ajayi & Falade [4] reported 81.1% respondents gave paracetamol to their febrile children before attending the general outpatient clinic in Ibadan, south west Nigeria whereas Daifallah et al [5] in Palestine reported majority of respondents (50.9%) administered paracetamol to reduce their children's fever while 15.3% administered it as an analgesic.

Paracetamol has been observed as the most widely used analgesic and antipyretic. [6] Obu et al [3] in their study in Enugu, south east Nigeria documented that 75.6% children were given paracetamol before presenting at the Paediatric outpatient clinic. A similar study by Fadare et al [7] in south west Nigeria also showed that majority (51.8%) children received paracetamol before presentation to the hospital. Mason et al [8] in Sheffield, UK documented that paracetamol was the first line antipyretic drug administered to children as also reported by Gehri et al. [9]

There are various formulations of paracetamol; this includes tablets, capsules, suppositories, soluble powders and liquids (syrups, drops & injections). It is pertinent to note that the suppository formulation is particularly important in children who are vomiting or have challenges with the oral formulation. The type of formulation used depends on the age of the child, severity of symptom(s) as well as the type of formulation available hence may vary with geographic locations. In Nnewi [3] south east Nigeria, oral formulation was the preferred route of pre-hospital paracetamol administration accounting for 98.9% while injection accounted for only 1.1%. In this study, of the oral formulation, tablets accounted for majority (49.2%) while syrups 38.7% and both 12.1%. Syrups were majorly used in children < 5 years while tablets

were used mostly in older children > 5 years. In contrast, a cross-sectional study in Palestine documented suppository (33.8%) paracetamol as the preferred formulation followed by syrups (25.4%) and drops (1.7%). [5] Similarly, suppository or the rectal administration of paracetamol was documented as the preferred route by Gehri et al [9] in under five children.

The recommended dose of paracetamol is 15mg/kg/dose and can be given 4-6 hourly. [1] It is very safe in children when given in the right dosage and timing however side effects can arise just like any other drugs especially in cases of overuse. The most common side effects of paracetamol are drowsiness, fatigue, rashes and itching. [10] Occasionally, children may also experience low blood sugar and tremors. [10] Serious side effects such as renal injury could arise when usage is prolonged and hepatic toxicity/liver failure and even death when over dose or high dose is given. [1],[6],[10] It is note-worthy that paracetamol is one of the commonest drugs given in over dose to children especially children below 6 years of age. [11],[12] Over dose of paracetamol is also common as paracetamol may be part of the components of other drugs such as medicines for cough, cold & flu, teething and migraine etc. [13] This is not surprising as these children in addition to paracetamol being given as an antipyretic/analgesics may also receive these medicines containing additional paracetamol thereby predisposing them to overdose. Paracetamol is said to be in high dose if dose administered is > 75mg/kg/day for at least 2 days. [14] Obu et al [3] in their study in Nnewi documented paracetamol misuse on children aged 6 weeks to 5 years in 1.7% of cases. Bilenko et al [15] in Isreal reported 34.8% respondents administered paracetamol to their children at doses higher than the recommended dose while 21.4% repeated the dose at intervals less than or equals 3 hours thus predisposing these children to adverse effects. Similarly, Daifallah et al [5] in

Palestine reported the time interval of paracetamol administration in 6.3% of children being less than the recommended at least 4 hours. Also, it has been observed that additional doses of paracetamol are frequently prescribed by health workers in the Paediatric emergency departments even when pre-hospital paracetamol was administered. [9] This therefore suggest that the dose given at home may have been inadequate or underdose.

Previous studies have shown that there is a gap in knowledge among mothers/caregivers concerning the rational use of paracetamol ie proper dose, its' administration, adverse effects and toxicity despite the fact that it is one of the commonest OTC drug being used. [3][5],[15-19] This has led to either under dosing or over dosing with its' attendant consequences. There is however paucity of information on this subject matter in Nigeria and no study of this kind has been carried out in Port Harcourt, the south south region of Nigeria. Thus, the present study was done to ascertain the pattern of pre-hospital use of paracetamol. Findings from this study will thus add to the body of knowledge. It will also help to strengthen policies that will educate mothers/caregivers and the public at large on the rational use of paracetamol including its' proper dosing, timing & routes of administration thereby reducing errors and the risk of adverse effects and toxicity.

Materials and Methods

It was a descriptive cross-sectional study among mothers/caregivers attending the Paediatric outpatient clinic of the Rivers State University Teaching Hospital (RSUTH) in Port Harcourt, south-south Nigeria carried out over six months from January 1st toJune 30th 2023. This State-owned tertiary hospital located in the Government reserved area of the State is a 375-bed hospital and receives referral from all the

Primary Healthcare centres and general hospitals in the 23 local government areas of the State as well as from private hospitals and neigbouringStates. The hospital consists of both non-clinical and clinical departments of which the Department of Peadiatrics is part.

The Paediatric outpatient clinic, one of the units in the Department of Paediatrics is open 5 days of the week, Mondays to Fridays from 8am to 4pm. It consists of the specialist clinics and the general paediatric clinics. Each clinic day is run by 2-3 consultants, resident doctors, house officers, nurses of various cadres, other non-medical support staff and sees 42 patients on average. Before the commencement of each clinic day, a health talk is usually given by the nurses and vital signs and anthropometric measurements taken.

A research assistant was recruited before commencement of the study. She was trained on the aim and objectives of the study, inclusion and exclusion criteria as well as the proper administration of the questionnaire to participants. A convenient sampling method was deployed for the study.

Ethical clearance was obtained from the RSUTH Ethics research committee. Mothers/caregivers were duly educated about the research in clear language they understood and a verbal consent whether or not to participate in the study was obtained.

All mothers/caregivers whose children were within the age group 1 month - 17 years were consecutively recruited for the study. The inclusion criteria included all mothers/caregivers of children 1 month – 17 years irrespective of their symptoms who gave consent to participate in the study whereas mothers/caregiverswho did not give consent to participate in the study were excluded from the study.

A pre-tested semi-structured questionnaire which was developed by the researchers was administered by the researchers and/or research assistant to the mothers/caregivers. Data collected included biodata of the patients and parents/caregivers as well as questions on the pattern of paracetamol administration to their children. Socio-economic class of the participants were determined using Oyedeji's classification[20]. Paracetamol was considered overdose if dose given was > 75mg/kg/day and underdose if dose given was < 10mg/kg/day.

Data was entered into an Excel sheet and analysed using SPSS software version 23. Data was presented as percentages, tables and figures.

RESULTS

A total of 401 parent/child pairs were recruited into the study. There were more males than females in a ratio of 1.4:1

SOCIO-DEMOGRAPHIC CHARACTERISTICS

The mean age of the children was 28.26 ± 3.80 months while the mean weight was 14.94 ± 2.06 Kg. The average age of the mothers was less than that of the fathers (35.48 ± 1.26 years versus42.11 ± 7.43 years). Most of the parents had tertiary level of education, were business men/women and belonged to the upper socioeconomic class.

Table 1: Socio-demographic Characteristics of Child

Variable	**Frequency (n = 401)**	**Percent**
Sex		
Male	235	58.6
Female	166	41.4
Child Age Group (months)	42.11 ± 7.43 years	

1 – 10	89	22.2
11 – 20	51	12.7
21 – 30	43	10.7
31 – 40	41	10.2
41 – 50	24	6.0
>50	153	38.2
Mean age: 28.26 ± 3.80 months		
Childs Weight Group (Kg)		
<4	12	3.0
4.1 – 14.0	176	43.9
14.1 – 24.0	121	30.2
24.1 – 34.0	32	8.0
>34.0	60	15.0
Mean weight: 14.94 ± 2.06 Kg		

Table 2: Parents' Socio-demographic Characteristics

Variable	**Frequency (n = 401)**	**Percent**
Mother's Age Group (years)		
<30	80	20.0
30 – 40	225	56.1
>40	96	23.9
Mean Age: 35.48 ± 1.26 years		
Mothers' Occupation		
Business/trader	166	41.4

Civil servant	59	14.7
Public Servant	58	14.5
Student	19	4.7
Hose wife/Unemployed	30	7.5
Artisan	33	8.2
Professional	36	9.0
Mothers' Level of Education		
Primary	5	1.2
Secondary	123	30.7
Tertiary	273	68.1
Father's Age Group (years)		
28 – 37	125	31.2
38 – 47	186	46.4
>47	90	22.4
Mean age: 42.11 ± 7.43 years		
Father's Occupation		
Business/ Trader	146	36.4
Civil servant	88	21.9
Public servant	34	8.5
Professional	52	13.0
Artisan	40	10.0
Unemployed	6	1.5
Private company employee	35	8.7
Level of Education		
Primary	4	1.0

Secondary	111	27.7
Tertiary	286	71.3
Socioeconomic Class (OYEDEJI)		
Class 1	102	25.5
Class 2	195	48.6
Class 3	86	21.5
Class 4	17	4.2
Class 5	1	0.2
Socioeconomic status(SES) #		
Upper	297	74.1
Middle	103	25.7
Lower	1	0.2

upper SES = class 1+2, middle SES = class 3+4, lower SES = class 5

Pre-hospital administration of paracetamol

About 40% of the children had received paracetamol before presentation at the hospital, the commonest reasons being for fever and cough and the least reasons being for body rash and covulsion. Syrup paracetamol was the most commonly administered formulation. No child received paracetamol suppository. The choice of fprmulation was based on the age of the child and available formulation at home. Medication was administered mainly twice or three times daly and 20% of the patients received paracetamol for seven days and above.

Table 3: History of Paracetamol Usage

Variable	**Frequency (n = 401)**	**Percent**

Administered Paracetamol		
Yes	162	40.4
No	239	59.6
Reason for Paracetamol		
(Multiple responses, n = 247)		
Body rash	3	1.9
Convulsion	4	2.5
Excessive crying	6	3.8
Fever	133	83.6
Cough	48	30.2
Body/Abdominal pain	17	10.7
Catarrh	17	10.7
Headache	9	5.7
Other reasons	10	6.3
Type of Paracetamol formulation		
(n = 162)		
Tablet	75	46.3
Syrup	86	53.1
Injection	1	0.6

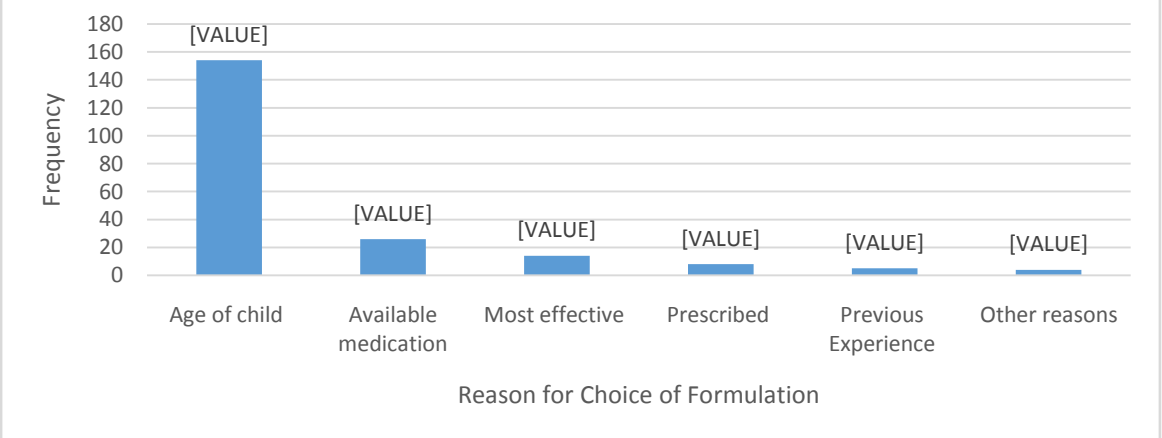

Figure 1: Reason for Choice of Formulation Used

Table 4: Administration of paracetamol

Variable	Frequency (n = 162)	Percent
Frequency of daily dosage for Paracetamol (n = 162)		
Once	42	26.8
Twice	62	37.8
Thrice	58	35.4
Duration of Paracetamol Medication (n = 160)	**Frequency (n =160)**	
< 7 days	128	80.0
≥ 7 days	32	20.0

Table 5: Person Responsible for Prescription

Variable	Frequency (n = 199)	Percent
Person Responsible for Prescription		
Doctor	50	25.1
Pharmacist	42	21.1
Chemist	14	7.0
Self-Experience	72	36.2
Nurse	17	8.5
others	4	2.0

Table 6: Additional Drugs Administered

Variable	Frequency (n = 204)	Percent
Drugs (multiple response)		
Antimalarial	47	36.2
Antibiotics	9	6.9
Vitamin C	59	45.4
Cough syrup	35	26.9
Blood Tonic	28	21.5
Multivitamins	6	4.6
Other drugs	21	16.2

Table 7: Drug Dose Perception

Variable	Frequency (n = 162)	Percent
Child Improvement After Drug Administration		

(n = 162)		
Yes	95	58.6
No	55	40.0
I Don't Know	12	7.4
Administered the Correct Dose (n = 162)		
Yes	97	59.8
No	9	5.6
I Don't Know	56	34.6
Appropriateness Paracetamol Dose(n =150)		
Yes	104	69.3
Under-dose	38	25.3
Overdose	8	5.4

DISCUSSION

This study discovered a high prevalence of pre-hospital administration of paracetamol among the respondents 162(40.4%). This is similar to the 51.8% reported in Ekiti, South West Nigeria[7]and 50.9% in Palestine,[5]56.9% in Mexico[23], 58% in India[24] but lower than the 67% reported earlier by Eberechi et al in Port Harcourt[25], the 75.6% reported by Obu et al in Enugu[3]and 81.1% in Ibadan by Ajayi et al[4].This high rate is not surprising because paracetamol is an OTC medication easily accessible and cheap enough for parents with ill children to give their children before coming to the hospital. The much higher prevalence in Ibadan[4] could also be explained by the fact that his study was among febrile children who are more likely to receive paracetamol before presentation to relieve fever. Parents also give paracetamol when they theink the illness is not serious enough to warrant taking the child to the hospital or when they think the hospital is too far.

Fever was the commonest reason for administration of paracetamol at home in this study as well as in previous reports[3,4,5,24,25,26]. Fever is a symptom of quite a number of diseases and parents are eager to ameliorate any discomfort as much as

they can hence the likely reason for administering paracetamol before bringing the child to the hospital. Other symptoms the children in this study had that necessitaed paracetamol administration were cough and body pains. Obu et al in Enugu[3], Danfallah et al in Palestine reported similar findings.[5]Parents' attempts at relieving symptoms with the easily accessible available and cheap paracetamol would most likely account for this.

The oral formulation was the more preferred route of administration as reported also in other studies.[3,4,7] Children younger than five years were likely to receive syrups while older children received tablets[3]. Oral formulations are more easily available, accessible and cheap. In this study rectal suppositories were not given although it was administered in 33.8% in Palestine.[5]Paracetamol suppository is as effective as other formulations and can be used when patients are too sick or are vomiting and in Switzerland[9]health care providers would chose it as their preferred route of administration. Ignorance about its availabilty and use may be the reason why it was not administered by parents/caregivers in this study as well as in the report from Sri Lanka[26]. The reason for this was not part of the objective of this study and so was not explored. Injectable formulation was the least used in this study as also reported in Enugu[3]This is not a surprise as it would require a trained healthcare personnel to administer it. Moreover parents would not want to add the pain of an injection to an already sick child if it is possible.

More than 70% of caregivers in this study gave paracetamol dose based on parents' experiences in this study similar to the report from Enugu[3] and Syri Lanka.[26]The source of paracetamol was mainly from patent medicine stores and pharmacies similar to earlier reports[3,7]

Most parents and caregivers (about 70%) in this study administered correct dose just like in reports elsewhere[3,7,8] Being a commonly prescribed medication within and outside healthcare facilities as well as the fact that dosing of the drug is on leaflets and body of the drug as well as many adverts on the use of paracetamol can explain this. Paracetamol misuse (underdose, overdose) was in 1.7% of children in Enugu[3]62% in America in children 10 years and below[21] and 53% by Goldman et al[22].In the study by Li et al in America[21] among children aged 10 years and below, over 62% of children received an inappropriate dose of paracetamol before presentation at the emergency department. Goldman et al[22] also reported that 26 parents (12%) gave an overdose, and 87 (41%) gave an underdose of acetaminophen. Bilenko et al[15] reported that 34.8% of parents gave an overdose to the children while 21.4% of the children in that study received the medication too frequently that is less than 4 hourly.In Syri Lanka, 11% of the children received an underdose while 43% received an overdose and 16% of the children were given more frequent than recommended.[26] Inappropriate dosing of paracetamol was also noted in this study with 25.3% (overdose) and 8% (underdose) as well as 32 children (20%) receiving paracetamol for more than seven days. Underdosing a medication will cause it to be ineffective for the ailment being treated while overdose in terms of quantity, frequency of administration and duration will predispose children to the complications of paracetamol. The assessment of such complications was beyond the scope of this study.

Another finding in this study was the co-administration of other medications at home with antimalarials (36.2%) haematenics(51.5%) and antibiotics (6.9%) being the most commonly administered medications. Fadare et al[7] in Ado-Ekiti reported similar co-administration (antimalarials 24.7%, antibiotics 14.8% and vitamins 8.7%)

while in Enugu South Esat Nigeria, half of children who received paracetamol at home also received other medications mainly antimalarials and antibiotics[3]. Parents/caregivers usually try to ameliorate symptoms at home and when they have a favourable response may not bring the child to the hospital.[22].They would however, take to the hospital with persistence or worsening of symptoms. Nigeria is in a malaria- endemic region with high disease burden for infections hence the reason for administration of antimalarials as well as antibiotics at home. This may lead to drug resistance if inappropriate doses are administered. Parents also feel that most drugs should be administered with haematenics to ensure proper absorption.

Conclusion

Administration of paracetamol to children at home before presentation at the hospital is a common practice among caregivers in this study. There is a need to educate caregivers on the proper dosing to avoid misuse which can lead to complications.

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