The Use and Abuse of Paracetamol in Children by Caregivers in Enugu, South-east, Nigeria

Obu H\textsuperscript{1}, Chinawa JM\textsuperscript{2}, Ubesie AC\textsuperscript{3}, Ekeh BC\textsuperscript{4}, Ndu I\textsuperscript{5}.

1. Senior Lecturer and consultant; University of Nigeria Enugu Campus; University Of Nigeria Teaching Hospital Ituku - Ozalla, Enugu.

2. Lecturer and consultant; University of Nigeria Enugu Campus; University Of Nigeria Teaching Hospital Ituku - Ozalla, Enugu.

3. Lecturer and consultant; University of Nigeria Enugu Campus; University Of Nigeria Teaching Hospital Ituku - Ozalla, Enugu.

4. Lecturer and consultant; University of Nigeria Enugu Campus; University Of Nigeria Teaching Hospital Ituku - Ozalla, Enugu.

5. Senior registrar; University of Nigeria teaching hospital Ituku Ozalla, Enugu

E-mail Addresses: josephat.chinawa@unn.edu.ng
herbert.obu@unn.edu.ng
zionagoz@yahoo.co.uk
chriseke2006@yahoo.com

Dr Herbert Obu
College of Medicine
Department of Paediatrics
University of Nigeria Enugu Campus
Enugu
Nigeria

Corresponding Author
Abstract

**Background:** Paracetamol (acetaminophen) is the commonest available analgesic and antipyretic. It is readily accessed from pharmacy shops, drug and provision stores as over the counter drug making it a potential drug of abuse. We sought to find its use and abuse by Caregivers presenting with their wards at UNTH Ituku/Ozalla, Enugu.

**Objective:** To determine the dosage, formulation, and frequency of Paracetamol administration by Caregivers; and factors that influence its use.

**Method:**

A cross sectional study involving 235 children and their Caregivers seen at the paediatric outpatient clinic of the University of Nigeria Teaching Hospital, Ituku Ozalla, Enugu between June and November 2011 using a pretested questionnaire after obtaining consent.

**Results:**

A total of 235 children aged six weeks to 16 years and their Caregivers participated in this study. The mean ages of the children and their Caregivers were 3.8 and 33.9 years respectively. The male children were 136 while females were 99. Most of the children (75.6%) received Paracetamol at home before presenting. Paracetamol tablet alone or in combination with the syrup was mostly used (60%) and cuts across all age groups. The commonest reason for using Paracetamol tablet instead of the syrup was that it was more effective. Most Caregivers relied on past experience (71.2%) rather on information leaflet to decide the appropriate dosage. Half of the children also received other medications which were mainly antimalarials and antibiotics.

**Conclusions:** Paracetamol is potentially being abused in children and Caregivers need to be educated about this urgently.

Key Words: Paracetamol; Children; Enugu
Introduction:

Acetaminophen is the most widely used analgesic and antipyretic.[1] It is found in many over the counter and prescription products. Given in the right dosage it is not associated with many side effects; however prolonged use may produce renal injury and massive overdose may produce hepatic injury. [1, 2] It is the most common pharmaceutical agent involved in overdose particularly below the age of 6 years. [3,4] There is a particularly significant risk of acetaminophen overdose in infants and children because of the varying dosing schedules and the variety of formulations with different strengths of liquids.[4] The easiest way to inadvertently overdose on acetaminophen is to combine various cough and cold medications because people are unaware that acetaminophen is present in many of them.[5] This study assesses the administration of acetaminophen to under 6 children to identify patterns and factors associated with overdose. The findings will help highlight the widespread practice of acetaminophen overdose in children and also create awareness of the seriousness of taking this common medication.

Paracetamol was discovered in Germany at the end of 19th century. Toxicity in Over –The-Counter (OCT) was noticed in 1960s and 1970s.[6]

PCM (Acetaminophen) is a weak inhibitor of the synthesis of prostaglandins. Nevertheless the in vivo effects of paracetamol are similar to those of selective cyclo-oxygenase-2 inhibitors.[7] These drugs are remarkably safe for children but serious side effects can occur when used inappropriately. However liver toxicity can occur with inappropriate use. For instance sustained high doses for a sick child under the age of two can lead to toxicity within days.[8]
Liver injury secondary to repeated dosing of paracetamol should be considered when a child has received more than 75mg/kg/day for at least two days or if risk factors for paracetamol toxicity is discovered.[9] Too much of paracetamol (PCM) can prove deadly especially for children.[10] Sydney hospital alone recorded 17 cases of liver failure in children from erratic prescription since 1985.[10] Due to self medication and inappropriate dosing, the incidence of poisoning has increased with attendant morbidity and mortality.[11]

More than 70% of population in western countries uses analgesics regularly mainly for headache, pains and febrile illnesses.[12] This could be due to pain and discomfort which is common in everyday life and are often treated with over the counter analgesics (OCT).[8]

PCM abuse has increased to 5 folds between 1978 to 1988 and has worsened to more than 200g/person/year.[13] In United Kingdom The rate of paracetamol purchased without prescription is reported to have increased to 3500 Million 5000mg tablets in the year 2000.[14] PCM overdose is a significant cause of Hospital admission but severe liver damage is infrequent and when it does occur the prognosis is good.[14]
METHODOLOGY

Study Area

The study was carried out at the children’s outpatient (CHOP) and consultants’ clinics of the Paediatrics Department of the University of Nigeria Teaching Hospital (UNTH) Ituku- Ozalla, Enugu, Nigeria.

Study Population

A cross sectional prospective study involving 235 children and their Caregivers seen at the paediatric outpatient clinic of the University of Nigeria Teaching Hospital, Ituku Ozalla, Enugu between June and November 2011 using a pretested questionnaire after obtaining consent. It is a referral centre for various health centers in Enugu state and environs. The Paediatrics Department comprises the children’s outpatient clinic (CHOP), the children emergency room (CHER), the general ward, and the new born special care unit (NBSCU). The children’s outpatient clinic runs every weekday and a total of 840 patients are seen monthly.

Ethical clearance for the study was sought from the Research and Ethical Committee of the University of Nigeria Teaching Hospital. A written consent was obtained from the parents/caregivers of the subjects and controls after explaining to them, in detail, the objectives of the study.

Data Analysis

Data was analyzed by SPSS version 13. An initial frequency count of all variables was done and represented in tables. The mean and ranges of all the variables were calculated. The Level of significance was set at $P \leq 0.05$. 

Aim: To determine the pattern and factors of acetaminophen administration to children by caregivers in Enugu, SE Nigeria.

Objectives:

1. To determine the pattern of acetaminophen administration to children by caregivers in Enugu, SE Nigeria.

2. To determine the factors that influence acetaminophen administration among children by caregivers in Enugu, SE Nigeria.

Inclusion Criteria

Children aged between 6 weeks and 16 years and whose caregiver or parents gave consent.
Results:

Demography

A total of 234 children were enrolled into this study. One hundred and thirty six were males while 98 were females giving a male: female ratio of 1: 0.7. The children were aged 6 weeks to 16 years. The mean age of the children was 3.8 ± 4.3 years. The most common age group in this study was under five years which represented 67.7% and 72.4% of males and females respectively. There was no statistically significant difference in the age and sex distribution of the children as shown in Table 1.

The Caregivers were aged 18 to 57 years. Most of them (90.3%) were females. The highest educational attainment of majority of the Caregivers (65.3%) was first degree of diploma. The rest had senior secondary (28.6%), primary (2.8%), junior secondary (1.4%) and post graduate education (1.4%). The various occupation of the Caregivers were civil servants (25.6%), unemployed (25.1%), trading (14.4%), teaching (13%), self-employed (7.9%), health care worker (6.5%), banker/marketer (3.7%) and others (3.6%). Among the Caregivers, 88.7% were mothers of the children, 7% were fathers, 1.7% aunts and 2.6% others (such as uncles, sisters, brothers).

Paracetamol Use:

Most of the children (75.6%) received Paracetamol at home before presenting at the Clinic. Among them, the most reason for administering Paracetamol was fever (68.4%). Other reasons were headache, abdominal pain or discomfort, cough as shown in Table 2.

Except for two children (1.1%) that received injectable paracetamol, oral administration was the preferred route (98.9%). The oral formulations used, were tablet (49.1%), syrup (38.7%) while 12.1% received both tablet and syrup.

Among children under the age of five, syrup formulation was most commonly used (50.4%) while tablet was most commonly used among those aged 5-10 (87.5%) and 11 to 16 years (92.3%) as shown in table III. There was a statistically significant difference between the age groups of the children and formulation used.
More than half of the respondents (59.5%) decided on their own to administer Paracetamol to their children. The rest received prescription from a doctor (26.3%), a nurse (8.6%) and from either a Patent Medicine Dealer or a Pharmacist (5.7%) as shown in Table IV. Most of them (71.2%) relied on past experience to arrive at the dose to be administered as shown in Table V.
DISCUSSION

This study helps to describe the pattern of paracetamol administration to children and the factors that influence it. Majority of our care givers gave paracetamol to their children for fever. Antipyretics including acetaminophen are prescribed commonly in children with fever, despite minimal evidence of a clinical benefit. No studies showed any clear benefit for the use of paracetamol in the therapeutic doses in febrile children.[15] Fever is a common symptom of childhood illness in both developed and developing countries and much time and effort is spent on attempts to reduce high temperatures in young children. Though the disease process that leads to fever may be harmful, no convincing evidence shows that fever it is harmful, despite this; many parents and physician believe that antipyretic treatment improves febrile children discomfort and behavior. Paracetamol is prescribed commonly therefore despite minimal data on clinical benefits. [15] The current guidelines of WHO on the management of fever recommends the use of paracetamol for children with a fever $\geq 39^\circ$C . However insufficient data supports this recommendation.

A randomized trial of paracetamol(10-15mg/kg/dose) every four hours versus Placebo in 225 febrile children with non bacterial infection showed no significant difference between treated and placebo groups in mean duration of fever or other symptoms.[16]

From this study majority of the paracetamol administered to our children are self prescribed with a possible tendency of abuse and overdose. Park [5] reported a growing concern over the drugs which can be given to children without the scripts when parents may not be fully aware of the potential risks. The use of paracetamol in therapeutic doses generally is safe, although hepatotoxicity has occurred with recommended dosages in children in developing countries. The
cost associated with prescribing paracetamol are not trivial for many families, no study showed any clear benefit for the use of paracetamol in therapeutic doses in children. A Cochrane review was unable to show a superior antipyretic effect with paracetamol compared to placebo. [17]

This study reiterates the fact that majority of childhood febrile illnesses are first treated at home using past experience on the dose of paracetamol given to their wards. The reason why mothers give paracetamol at home before presenting to the hospital is that it gives them the feeling of mastery. It was also suggested that it gives the child rest and sleep and enables the family to rest too. [18] A Cross sectional survey of consenting guardians of 535 consecutive febrile children under 10 years presenting at General Outpatients' (GOP) Clinic, University College Hospital Ibadan was carried out by Ajayi et al [10]; most 469 (87.7%) respondents gave drugs bought from chemists/pharmacy shops before presentation at the GOP. Paracetamol 1380 (81.0%) and chloroquine [171 (36.5%)] were the most commonly used drugs. It underscores the need to empower caregivers by appropriate education.

It is pertinent to note that previous official guidance opined that children aged from 1-6 years could be given up to 10 mls of liquid paracetamol 4 times a day to reduce fever and pain, but now medications and health care regulatory agency(MHRA) has divided children into more detailed age brackets with specified doses for each. For instance all the previous doses given to children are now halved. [11]

We recommend that health professional should not be encouraged to give antipyretics routinely to febrile children. Treatment should only be given to those children in obvious discomfort or with painful conditions. Mothers and care givers should seek advice from doctors or trained health officials before giving these drugs to their wards.
Conclusion: Paracetamol is potentially being abused in children and Caregivers need to be educated about this urgently.
REFERENCES


12. Sheen CL, Dillon JF, Batemen DN, Simpson KJ, Macdonald TM.


**TABLES**

Table I: Age and sex distribution of the children

<table>
<thead>
<tr>
<th>Age of Clients (years)</th>
<th>Male (%)</th>
<th>Female (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 5</td>
<td>90 (67.7)</td>
<td>71 (72.4)</td>
</tr>
<tr>
<td>5-10</td>
<td>30 (22.6)</td>
<td>17 (17.3)</td>
</tr>
<tr>
<td>11-16</td>
<td>13 (9.7)</td>
<td>10 (10.3)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>133 (100)</strong></td>
<td><strong>98 (100)</strong></td>
</tr>
</tbody>
</table>

χ² = .948, df = 2, p = 0.623

Table II: Reasons for Administering Paracetamol

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>145 (68.4)</td>
</tr>
<tr>
<td>Cough and/or Catarrh</td>
<td>17 (8)</td>
</tr>
<tr>
<td>Abdominal pain/discomfort</td>
<td>9 (4.2)</td>
</tr>
<tr>
<td>Ear ache</td>
<td>8 (3.8)</td>
</tr>
<tr>
<td>Skin rash</td>
<td>6 (2.8)</td>
</tr>
<tr>
<td>Generalized body pains</td>
<td>5 (2.4)</td>
</tr>
<tr>
<td>Fast/difficulty in breathing</td>
<td>4 (1.9)</td>
</tr>
<tr>
<td>convulsions</td>
<td>3 (1.3)</td>
</tr>
<tr>
<td>Others (injury, tooth ache, excessive crying, vomiting)</td>
<td>6 (2.6)</td>
</tr>
</tbody>
</table>
Table III: Relationship between age and formulation of Paracetamol administered.

<table>
<thead>
<tr>
<th>Age of Clients (years)</th>
<th>Less than 5 (%)</th>
<th>5-10 (%)</th>
<th>11-16 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablet</td>
<td>45 (35.4)</td>
<td>28 (87.5)</td>
<td>12 (92.3)</td>
</tr>
<tr>
<td>Syrup</td>
<td>64 (50.4)</td>
<td>2 (6.3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>tablet and syrup</td>
<td>18 (14.2)</td>
<td>2 (6.3)</td>
<td>1 (7.7)</td>
</tr>
<tr>
<td>Total</td>
<td>127 (100)</td>
<td>32 (100)</td>
<td>98 (100)</td>
</tr>
</tbody>
</table>

\[ \chi^2 = 39.2, \text{ df} = 4, \text{ p} = 0.00 \]

Table IV: Source of the Paracetamol Prescription

<table>
<thead>
<tr>
<th>Prescriber</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>46 (26.3)</td>
</tr>
<tr>
<td>Nurse</td>
<td>15 (8.6)</td>
</tr>
<tr>
<td>Patent Medicine Dealer/Pharmacist</td>
<td>10 (5.7)</td>
</tr>
<tr>
<td>Self</td>
<td>104 (59.5)</td>
</tr>
</tbody>
</table>
Table V: Determination of dose administered

<table>
<thead>
<tr>
<th>Method of dose determination</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directions on the medication</td>
<td>29 (26.1)</td>
</tr>
<tr>
<td>Past experience</td>
<td>79 (71.2)</td>
</tr>
<tr>
<td>Health care workers</td>
<td>3 (2.7)</td>
</tr>
</tbody>
</table>
Additional files provided with this submission:

Additional file 1: ACETAMINOFEN TABLES.rtf, 97K
http://www.biomedcentral.com/imedia/1660155307691794/supp1.rtf