Neonatal and Pediatric Medicine

Effectiveness of a Single Dose of Oral Vs Rectal Paracetamol in Reducing Fever in Children Aged Between 2 to 6 Years – A Randomized Controlled Trial

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Abstract

Background:

Methods:

arm. The frst arm received single doses of 15 mg/kg oral paracetamol and second group received single doses of 30 mg/kg rectal paracetamol. A data extraction sheet was to record temperature at baseline and at 15 minutes, 30 minutes, 1 hour, 1 and1/2 hours, 2 hours, 2 and ½ hours and 3 hours after administration of the drug. The rate of temperature

Results: In the oral group, mean temperature reductions at 15 minutes, 30 minutes, 1 [illegible] 1 and 2nd [illegible] When compared the means of both groups there was statistically signifcant diference between two groups in all the time periods (P<0.05) except at 1 hour after administration of paracetamol (P = 0.06). There was no statistical signifcant diference in side efects when comparing two arms as well.

Conclusion: A single dose of 30 mg/kg rectal paracetamol is more efective than single dose of 15 mg/kg oral paracetamol in reducing fever. There is no diference in relation to the safety of the two routes.

Trial registration: SLCTR, SLCTR/2017/025. Registered 17 August 2017-Retrospectively registered, https://slctr.lk/ SLCTR/2017/025

Ke ords: Paracetamol; Oral; Rectal; Temperature; Fever

Abbreviations

PCM: Paracetamol

Introduction

Fever has become one of the most common clinical symptoms managed by the paediatricians and health care providers today. It is usually a natural reaction to infection. However, some other factors can raise the body temperature as well. In management of fever, clinicians commonly advice on temperature control via the use of over-the-counter antipyretics [1].

When children get fever, parents usually su er from "fever phobia" [2,3]. Fever phobia is exaggerated fear of parents whose child have fever. It's actually a misconception of parents that fear is not dependent on socio-economic status of parents [4]. Most of the parents think that with high fever child can get serious neurological complications [5]. Parents are very much concerned to maintain normal temperature in their ill child.

Paracetamol is the most widely used drug for reducing fever in children [1,6]. It is safe in standard doses of 60 mg/kg/day and could be used either rectally or orally. [1,6,7,8] ough the oral route is the most commonly used, in some circumstances, the rectal route is preferred. Examples include; a child with febrile convulsion, fever with repeated vomiting, and high-grade fever without tolerating oral medication. It has been shown that oral paracetamol is absorbed within 30 to 60 minutes of ingestion. Pharmacokinetic properties of single dose of oral paracetamol are well studied. Nevertheless, pharmacokinetics of paracetamol when administered via rectal route is not well established. Its absorption is prolonged and depends on the size of suppository, base composition, and rate of dissolution. Moreover, some evidence has revealed that antipyresis serum concentration of 15 – 20 microgram/ml could not be achieved by rectal dose of 10 – 15 mg/kg and a rectal dose of 30 - 45 mg/ kg is needed [9,10].

Although several studies have been done, it has not been absolutely documented whether equal dose of rectal and oral paracetamol have similar e ectiveness in reducing fever. Results of published studies comparing the e ectiveness of these two preparations are not uniform.

Some shows oral administration of paracetamol was more e ective than the rectal format, whereas other researchers reported that both have similar e ectiveness. [1, 8,11,12,13,14] A meta-analysis shows that

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there is no di erence in e ectiveness of temperature reduction between oral and rectal paracetamol [15]. e widely used standard anti-pyretic dose of oral paracetamol is 15mg/kg/dose [19]. e standard anti-pyretic dose of rectal paracetamol is 30mg/kg as a single dose and then 15- 20 mg/kg every 4-6 hours as necessary [16]. is is the rst ever clinical trial to compare the e ectiveness of oral vs rectal paracetamol in reducing fever in the South Asian region according to literature.

Aim of this study was to compare the antipyretic e ectiveness (rate of temperature reduction) and the side e ects of single dose of 15mg/kg paracetamol given orally with that of 30 mg/kg given rectally in children aged 2-6 years and the null hypothesis of the study was that there would be no statistically signi cant di erence in the antipyretic e ectiveness between oral paracetamol given at 15 mg/kg and rectal PCM given at 30 mg/kg.

Methods

Trial design

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normal and high dose rectal paracetamol in the treatment of febrile children, conducted by Scolnik D et al, demonstrated that there was no di erence in temperature reduction in patients treated with 15 mg/kg oral paracetamol and the same or double dose rectally. Even in this study the sample size was not satisfactory, and they had recruited 23, 23 and 24 children to each group. It is not a blind study as well. Another randomized, double-dummy, double-blind study of 51 febrile children, receiving one of three regimens of a single paracetamol dose of 15 mg/kg orally and 15 mg/kg rectally, or 35 mg/kg rectally revealed that they have similar antipyretic e ectiveness. [12] Even though this is a double- blind study, there were only 16 – 18 participants in each group. Moreover, there was a wide age range of 6 months to 13 years in participants as well.

A meta-analysis done in 2008 by Lee Hilary Goldstein et al, revealed that there was no di erence in oral and rectal paracetamol in fever reduction. [15] A research done to nd out the e ectiveness of rectal paracetamol in small children with fever in 1979 using 37 febrile children aged between 3 months to 6 years also showed that both have equal antipyretic e ectiveness. [13] A study done by Hopkins CS, Underhill S, Booker PD et al, to evaluate the pharmacokinetics of paracetamol a er cardiac surgery using 28 febrile children aged between 9 days to 7 years also demonstrated that there was no di erence in antipyretic e ect between the two routes of administration. [14]

According to the literature, there was only one study which had somewhat similar ndings to our study. at was a randomized controlled trial conducted by Chomchai et al in a paediatric acute care setting on 2015 in Bangkok, ailand. It revealed using rectal paracetamol in an acute situation with tepid sponging, can e ectively reduce fever and keep body temperature down longer than oral paracetamol. [19] In this study, the sample size was 200, which is much higher in number when compared with all the above-mentioned studies.

Limitations of the study were: we conducted a single blinded trial where only the principal investigator was unaware about the treatment modality. If we conducted a double blinded trial, the ndings would have been much more accurate. ere was also a signi cant di erence in mean age between two arms though the allocation was randomized. However, the impact of this on temperature reduction was unclear. In addition, we conducted this study in children aged between 2-6 years only and e ects of oral and rectal paracetamol in fever reduction in neonates, infants, children aged between 1-2 years and children over 6 years were not assessed. erefore, further research will be necessary to evaluate the antipyretic e ectiveness in these age groups.

Conclusion

A single dose of 30 mg/kg rectal paracetamol is more e ective than a single dose of 15 mg/kg oral paracetamol in reducing fever. Occurrence of adverse events is seemingly similar in both groups. erefore, we recommend rectal paracetamol over oral paracetamol for fever control in children especially when oral drugs are not tolerated and in acute paediatric settings like febrile status epilepticus where administration of oral paracetamol is di cult.

Declaration

Ethical approval and consent to participate

is study was approved by Ethical Review Committee of Faculty of Medicine, University of Kelaniya (Reference Number: P/103/03/2017). e trial was registered in Sri Lanka Clinical Trial Registry (SLCTR/2017/025). e study was performed a er the parents of participants were fully informed. All the parents of the participants and signed an informed consent form and received written and verbal information before participating in this study.

Consent for publication

Not applicable.

Availabilit of data and materials

All data or analysed during this study are included in this published article.

Competing interests

e authors declare that they have no competing interests.

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Authors' contributions

NI & LF designed and coordinated the implementation of the study. NI was responsible for data acquisition and dra ed the manuscript. All authors reviewed and revised the manuscript, providing important intellectual content, and approved nal version.

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e presentation of the manuscript is in Research Square. [20]

Consort guidelines

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