VIEWPOINT

Paracetamol: The Double-edged Sword Available over the Counter

Shivali Shamsher[1], Thiagarajan Praba[2], Koyalmannam R Sethuraman[3], Shilpa Shamsher[4]

Abstract

Paracetamol is one of the most widely used drug available over the counter (OTC) which is persistently and heavily promoted by the catchy advertisements all around us. Surprisingly, it is one of the most common drugs for suicide as well. Shockingly, paracetamol causes hepatotoxicity even at therapeutic doses, which has led some national formularies to recommend dose reductions. This article aims to highlight the aspects which are not in the limelight of this widely available OTC medication. In addition to creating awareness, we also suggest implementation of laws to reduce the risks of deliberate and accidental overdose.

Keywords: Drug toxicity, Over the counter, Paracetamol, Safe drug dispensing.

SBV Journal of Basic, Clinical and Applied Health Science (2019): 10.5005/jp-journals-10082-02206

Paracetamol (PCM) was discovered in 1877, since then has been widely used as easily available over the counter (OTC) antipyretic and analgesic for all ages.[1] It occupies step 1 of World Health Organization (WHO) analgesic ladder and pivot role in multimodal analgesia.[2] So much so, that it is also in WHO's Essential Medicine List, the most effective and safe medicines needed in a health system.[3] PCM is available as a generic medication with numerous trade names. Monthly index of medical specialties search shows 61 formulations of PCM. It is an essential drug and many countries do not have rules and regulations controlling its sales and purchase.

Ironically, PCM is also one of the most commonly used drugs for intentional overdoses.[4] On investigating the reason behind the use of PCM for suicide, the results revealed its easy availability and inexpensiveness, knowledge of liver failure and ultimately death. They were not aware of the slow death due to multi-organ failure. Consumers were under the impression that they would immediately die after PCM overdose, if they knew about the slow death (due to multi-organ failure), they would not have preferred it.[5,6]

In UK, after the implementation of laws on PCMs sales and restricting the number of tablets per pack and restricting the number of packs sold per person with and without prescription at pharmacy and local shops without pharmacist, reduced the number of PCM tablets consumed in acute phase of depression for suicide (intentional overdose) and liver transplants cases following over dose and toxicity.[7]

In India also, PCM is the preferred OTC drug for pain or fever before visiting a doctor. Promotion of PCM has been prohibited by antiquated laws. Nonetheless producers promote PCM for all kinds of aches and pains including musculoskeletal pain (even though PCM has very little anti-inflammatory activity).[1,2,8]

PCM is advertised widely but the information provided gives only the temporary relief benefits, the advantages and not the disadvantages, harmful effects and the long term consequences. A study in 2015, showed Malaysian consumers had little knowledge about the consequences of PCM over consumption.[9]

In addition, as there are a lot of combination drugs, unintentional inadvertent overdose can happen due to unawareness of the total dose consumed per day.

Hepatotoxicity due to PCM even with in the therapeutic doses has also been reported in specific situations (with concurrent alcohol intake, combination with other hepatotoxic drugs and other liver diseases)[2] and led to the reduction of maximal total daily dose from 90 mg/kg/day to 75 mg/kg/day.[10] Even in the WHO Essential Medicine List, 20th latest version has new formulation of PCM 120 mg/5 mL as compared to 125 mg/mL in 19th edition. An FDA advisory committee in US in June 2009 recommended to reduce the maximum dosage from 1,000 to 650 mg, while combinations of PCM and opioid analgesics would be prohibited.[11] In January 2011, the FDA asked manufacturers of prescription combination products containing PCM to limit its amount to no more than 325 mg per tablet or capsule and began requiring manufacturers to update the labels of all prescription combination PCM products to warn of the potential risk of severe liver damage.[12] In November 2011, the medicines and healthcare products regulatory agency revised UK dosing of liquid PCM for children.[13]

[1,2]Department of Anaesthesia, Faculty of Medicine, AIMST University, Kedah, Malaysia

[3]Department of Medicine, AIMST University, Kedah, Malaysia

[4]Intensive Care Department, The Queen Elizabeth Hospital, Woodville, Australia

Corresponding Author: Shivali Shamsher, Department of Anaesthesia, Faculty of Medicine, AIMST University, Kedah, Malaysia, Phone: +60 124987687, e-mail: shivalibernard@gmail.com

How to cite this article: Shamsher S, Praba T, Sethuraman KR, Shamsher S. Paracetamol: The Double-edged Sword Available over the Counter. J Basic Clin Appl Health Sci 2019;2(2):79–80.

Source of support: Nil

Conflict of interest: None

Summary and Recommendations

Considering the damage caused by PCM and enormous work done in developed countries to reduce it, it is high time to make strict similar laws regarding its purchase (OTC) and inform the public regarding its overdose consequences even in developing countries by giving a true detailed picture of the drug profile. Public awareness regarding the adverse effects should be emphasized. As per its easy availability being one of the reasons

for its use for suicide in acute depressive illness, individually foiled packed tablets can be a solution as it takes time to open during which the impulsive drive of suicide can fade away. Last but not the least strict laws on the number of tablets/packs sold OTC should be reinforced.

References

1. Mangus BC, Miller MG. Pharmacology application in athletic training. FA. Davis Co; vol. 86; 2005. pp. 460–461.
2. Sharma CV, Mehta V. Paracetamol: mechanisms and updates. Cont Educ Anaesth Crit Care Pain Med 2014;14:153–158. DOI: 10.1093/bjaceaccp/mkt049.
3. WHO Model List of Essential Medicines (19th List). World Health Organization. Available at https://www.who.int/medicines/publications/essentialmedicines/en/, (accessed on 9 February 2019).
4. Kaur A, Thanasan S, Ng CG, Zainal NZ. P03-295 – Paracetamol as the major contributing factor in parasuicides in a single centre in Malaysia. Eur Psychiatry 2010;25:1363. DOI: 10.1016/S0924-9338(10)71349-3.
5. Gazzard BG, Davis M, Spooner J, Williams R. Why do people use paracetamol for suicide? Br Med J 1976;1:212–213. DOI: 10.1136/bmj.1.6003.212.
6. University of Oxford Centre of Suicide Research. Use of paracetamol for suicide and non-fatal self-poisoning, and evaluation of the effects of legislation on paracetamol and aspirin pack sizes; Available from http://cebmh.warne.ox.ac.uk/csr//resparacet.html, (accessed on 9 February 2019).
7. Fall in paracetamol deaths 'linked to pack limits'. Available from https://www.bbc.com/news/health-21370910, (accessed on 9 February 2019).
8. Gulhati CM. Don't pop that pill: Here's why you must avoid paracetamol for back pain. Available at https://www.indiatoday.in/lifestyle/health/story/paracetamol-for-back-pain-heres-why-you-must-avoid-it-282264-2015-07-14, (accessed on 9 February 2019).
9. Tan SF, Chong CP, Chooi W-T. An Evaluation of Practices, Perceptions and Understanding About Use of Acetaminophen (Paracetamol) Among Malaysian Consumers: A Qualitative Study. Mali J Pharm Sci 2015;13:25–41.
10. Moriarty C, Carroll W. Paracetamol: pharmacology, prescribing and controversies. Arch Dis Child Educ Pract Ed 2016;101:331–334. DOI: 10.1136/archdischild-2014-307287.
11. Foxhall K. FDA May Restrict Acetaminophen.WebMD. Available at https://www.webmd.com/pain-management/news/20090701/fda-may-restrict-acetaminophen#1, (accessed on 9 February 2019).
12. FDA Drug Safety Communication: Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure. U.S. Department of Health and Human Services, U.S. Food & Drug Administration. Available at https://www.fda.gov/Drugs/DrugSafety/ucm239821.htm, (accessed on 9 February 2019).
13. Liquid Paracetamol for Children: revised UK dosing instructions have been introduced. Mhra.gov.uk. 2011. [document on the Internet]. Available from https://web.archive.org/web/20111114224356/http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con134921.pdf (accessed 9th February 2019).