Paracetamol: The Double-edged Sword Available over the Counter

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Abstract

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. It occupies step 1 of World Health Organization (WHO) analgesic ladder and pivot role in multimodal analgesia. So much so, that it is also in WHO’s Essential Medicine List, the most effective and safe medicines needed in a health system. 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. 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.

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.

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).

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.

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) and led to the reduction of maximal total daily dose from 90 mg/kg/day to 75 mg/kg/day. 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. 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. In November 2011, the medicines and healthcare products regulatory agency revised UK dosing of liquid PCM for children.

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