

Paracetamol no worse than ibuprofen in children with mild asthma



Paracetamol (acetaminophen) is not associated with a higher incidence of asthma exacerbations or worse asthma control than ibuprofen in children with mild persistent asthma, according to findings from a 1-year randomised, double-blind trial.

Data from observational studies have suggested an association between paracetamol use (for pain or fever relief) and concurrent asthma symptoms in children; however, this association had not been investigated in appropriately designed trials until now. In this study, Wanda Phipatanakul (Harvard Medical School, Boston, MA, USA) and colleagues randomly assigned 300 children aged 12 to 59 months with mild persistent asthma to be given an oral suspension of either paracetamol (160 mg/5 mL) or ibuprofen (100 mg/5 mL) when needed to relieve fever or pain over 48 weeks. The primary outcome was

the number of asthma exacerbations per participant, defined as a clinically significant increase in symptoms that led to treatment with systemic glucocorticoids, and measured over 46 weeks to account for any other drugs used during the run-in phase.

The mean number of exacerbations did not differ between treatment groups: 0.81 (95% CI 0.65–1.02) with paracetamol and 0.87 (95% CI 0.69–1.10) with ibuprofen (relative rate 0.94 [95% CI 0.69–1.28]; $p=0.67$). Additionally, the number of days on which asthma was controlled did not differ between treatment groups (85.8% with paracetamol versus 86.8% with ibuprofen; $p=0.50$), adverse events did not differ between treatment groups, and no deaths occurred during the study. Phipatanakul commented, "Given that acetaminophen and ibuprofen are the only therapies available in this age group for pain and fever, and asthma

is so common, our findings should be of interest to all clinicians and families worldwide." She continued "Future studies in older children or those with more severe asthma might be helpful. For now, I think [our findings provide] assurance that acetaminophen is safe if used as directed."

William Cookson (Imperial College London, London, UK) added "A [previous] study raised a concern that giving paracetamol to children might increase their risk of asthma, but no plausible mechanism for this was offered. The authors of this study have carried out a meticulous prospective trial of children with asthma, which showed no difference between paracetamol and ibuprofen. Parents and physicians should be happy that they are doing no harm by giving orthodox doses of paracetamol to children with asthma."

Priya Venkatesan



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Published Online
August 31, 2016
[http://dx.doi.org/10.1016/S2213-2600\(16\)30269-7](http://dx.doi.org/10.1016/S2213-2600(16)30269-7)

For the study by Phipatanakul and colleagues see *N Engl J Med* 2016; 375: 619–30

FDA approves first generic version of Tamiflu



On Aug 3, 2016, the US Food and Drug Administration (FDA) announced the approval of the first generic version of Tamiflu (oseltamivir phosphate; Roche, Basel, Switzerland). The newly approved generic has been approved for treatment of influenza A and B in patients aged 2 weeks or older who have had influenza symptoms for up to 48 h and in patients aged 1 year or older for prevention of influenza.

The FDA states that it does not know whether oseltamivir is "effective in people who start treatment after 2 days of developing symptoms, or have weakened immune symptoms". Jonathan Ball (University of Nottingham, Nottingham, UK) told *The Lancet Respiratory Medicine*: "Oseltamivir can be used as the first line of defence against influenza strains that we don't have a vaccine for,

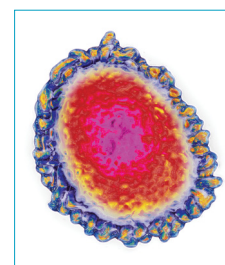
and to treat those who are more prone to developing severe influenza symptoms". He continued, "If given during the first 48 h after infection, it can reduce the severity of symptoms and shorten their duration; however, some studies have shown that, in otherwise healthy individuals, symptoms might only be shortened by around 1 day." Wendy Barclay (Imperial College London, London, UK) added, "Oseltamivir has been suggested to have only a slight benefit; however, this is mostly because it is difficult to give the drug early during infection as viral replication might peak before a patient realises that they are infected".

Ball outlined the need for caution when prescribing oseltamivir: "The worry is that approval of a generic version, which will make oseltamivir

cheaper, could encourage more widespread use and this could generate drug-resistant influenza strains. This could be a problem in individuals with severe symptoms—ie, those with comorbidities—because if infected with a drug-resistant influenza virus, they wouldn't gain any benefit from the drug."

However, if used appropriately and rapidly, as John Oxford (Queen Mary College, London, UK) says, "Oseltamivir can be used to treat serious cases and prevent deaths in high-risk communities". Barclay added, "If a patient is ill enough to present at hospital, a drug such as oseltamivir could save lives, and its availability as a generic medicine will hopefully mean it is used when appropriate."

Patricia Lobo



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Published Online
August 23, 2016
[http://dx.doi.org/10.1016/S2213-2600\(16\)30268-5](http://dx.doi.org/10.1016/S2213-2600(16)30268-5)

For the FDA news release see <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm514854.htm>

For the study on oseltamivir see *Cochrane Database of Syst Rev* 2014; 4: CD008965