Incomplete Case Report and Misleading Publicity

To the Editor:

Because upper respiratory tract infections (URTIs) are self-limited, the medications used to treat them must be safe and effective. Coinciding with media reports, I read the publication regarding Vicks VapoRub (VVR). As a pediatrician conducting trials on cough and cold medicines for children, I have criticized the limited evidence for these products. However, I found the current publication and press release incomplete and misleading with exaggerated or inaccurate statements.

First, I was disappointed by the case report’s missing data. Given the child’s age, the presence of cold symptoms, the concern for an asthma exacerbation, the lack of effect of albuterol and prednisolone, and the improvement of the child’s condition with oxygen therapy, it is unclear why bronchiolitis was not entertained as a diagnosis. Respiratory syncytial virus, influenza, and other viral test results are absent. Since bronchiolitis commonly causes asthma-like respiratory distress and because adverse events with the use of VVR are exceedingly rare, the omission of this information limits one’s ability to determine causality. While the distress was reportedly of rapid onset, this was based on a subjective medical history from grandparents who did not follow label instructions. This case report must be compared with extensive safety data demonstrating that in the past 5 years > 1 billion units have been sold with fewer than three adverse events reported per million units sold (Procter and Gamble Company; personal communication; January 12, 2009).

Next, beyond obvious differences between an 18-month-old child with a URTI who had VVR applied to nostrils and (1) excised ferret tracheas bathed in high concentrations of VVR and (2) intubated adult ferrets with medication applied to the endotracheal tube, the study title and conclusions do not match the results. Particularly for the in vivo studies, there was no significant increase in mucin production over baseline nor were there significant changes to mucociliary transport velocity (except in the lipopolysaccharide model) and lung water. However, in the summary statement in the article, the authors wrote that VVR leads to “increasing mucus secretion while decreasing mucus clearance,” but prior to this they had admitted their findings are not statistically significant. Therefore, the statement is not supported by in vivo data. The statement and manuscript title can therefore be considered misleading.

Last, regarding the statement that “fooling the brain into perceiving increased airflow,” achieving symptomatic relief of pain with nonsteroidal antiinflammatory drugs or opiates could also be characterized as “fooling the brain.” As with analgesia, most individuals welcome subjective symptom relief from URTIs. To that end and to report safety and efficacy evidence in children, we are conducting a trial on the effectiveness of VVR in children with URTIs that is being funded through an unrestricted grant from Procter and Gamble.

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Response

To the Editor:

I thank Dr. Paul for his passionate interest in our article. He appears to have four concerns with this publication. The first of these is that case report data were “missing” and viral test results were absent, leading to a misdiagnosis. This child presented to the emergency department (ED) in midspring when the positive predictive value of respiratory syncytial virus (RSV) testing is compromised by low background prevalence. Thus, RSV testing during the summer is not recommended. More important is that the results of RSV testing would be irrelevant. Vicks VapoRub (VVR) [Procter & Gamble (P&G); Cincinnati, OH] was used because this infant had symptoms of a viral infection. Her subsequent problem was consistent with our studies in the ferret showing that the mucociliary disruption caused by VVR was most detectable in animals with airway inflammation induced by endotoxin (lipopolysaccharide). These grandparents brought their granddaughter to the ED because of a sudden and rapid deterioration. Dr. Abanses was concerned about the possibility of foreign body aspiration. When he asked these astute grandparents to tell him what occurred that could have precipitated this sudden change, they volunteered that the deterioration occurred a very shortly after VVR was placed under her nose. The rapid deterioration and the rapid and complete resolution within hours are not consistent with the natural history of bronchiolitis or other respiratory virus infection. To suggest that these grandparents are unreliable witnesses because they had not read fine print warnings on the jar of VVR is absurd.

Dr. Paul’s second concern is with the results of the animal studies. Rather than just preparing a case report, we wish to determine if there was a plausible mechanism to explain how VVR caused this problem. Our ferret studies clearly show a dose response to VVR, leading to mucus hypersecretion and disruption of mucociliary clearance consistent with acute inflammation, with changes being seen even at a lower aerosol concentration than that encountered by this child. As detailed in the article, the ferret is a well-accepted model system for evaluating airway inflammation and mucociliary function. Although these results were clear and consistent with VVR contributing to inflammation-induced mucociliary dysfunction, we deferred the submission of this manuscript to see whether knowing about this problem would help our ED physicians recognize this in other children. Over the next 2 years, additional children presented with similar complaints also associated with the nasal use of VVR. At this point, we submitted this manuscript to allow physicians and parents to be aware of this problem.

References


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