TRIAL: Vapor Rub, Petrolatum and No Treatment for Children with Nocturnal Cough and Cold Symptoms

**Bottom Line:** Reassure parents that colds in young children are generally self-limiting. New evidence suggests that vapor rub (VR) is effective at providing symptomatic relief of nocturnal cough, congestion and sleep difficulties in children > 2 years of age, as compared to petrolatum or no treatment. However, consideration should be give to limitations: duration of study was only 1 night, small population, potential for loss of blinding, funding source (makers of VICKS VAPORUB) and use of subjective parental assessment as the primary outcome. If parents decide to use VR, inform them it is common for children to experience mild irritant effects (~15-30%) such as burning skin, eyes, and/or nose. Continue to recommend routine comfort measures (e.g. humidifiers, saline nasal spray) for symptomatic relief.

**Background:** The Health Canada restrictions for use of OTC cough and cold medications in treating young children, leaves many parents wondering what they can do to help their little one feel better.

**The Trial:**
- Partially double-blinded, randomized, single-night study design with 138 children, stratified by age (mean 5.8 ± 2.8 yrs).
- Included: ages 2 to 5 yrs and 6 to 11 years, with URI sx of cough, congestion and rhinorrhea lasting 7 days or longer.
- Excluded: hx of asthma, chronic lung disease, or seizure disorder, signs/sx of a more treatable disease (e.g. sinusitis, pneumonia, allergic rhinitis). Excluded if child was given selected OTC or Rx meds on the night before enrollment (e.g. pseudoephedrine, dextromethorphan, honey). Those enrolled were to avoid these specified meds as well.
- Acceptable routine care included: hydration, saline nasal spray not within 1 hr hs or throughout nights and use of acetaminophen or ibuprofen for comfort. Parents were instructed to avoid giving their child caffeinated beverages within 4 hours <hs.
- Surveys were administered to parents on 2 consecutive days; 7-point Likert-scale - subjective assessment of child’s sx.

<table>
<thead>
<tr>
<th>Study Arm</th>
<th>Ingredients</th>
<th>Dose Volume</th>
<th>Parental Blinding (high potential for bias)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VR oint</td>
<td>4.8% camphor, 2.6% menthol, and 1.2% eucalyptus oil</td>
<td>5 mL (2-5 yrs)</td>
<td>parent given cup filled with VR; 30 min &lt; hs parent applied VR below their nose prior to opening child’s tx cup; child &amp; family asked not to comment on tx odor</td>
</tr>
<tr>
<td>Petrolatum oint</td>
<td>100% pure white petrolatum jelly</td>
<td>10 mL (6-11 yrs)</td>
<td></td>
</tr>
<tr>
<td>No Treatment</td>
<td>investigator blinded: all grps received an opaque bag with tx cups inside; cohort unblinded</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*There were no significant differences found in baseline symptom-severity between the groups.

**Results:** [Note: within each study group, sx improved on the 2nd night; all children had a doctor visit between study nights]

<table>
<thead>
<tr>
<th>Nocturnal URI Symptoms</th>
<th>Statistically significant differences for between-night 7-Point Likert scale changes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>VR vs. no-tx</td>
</tr>
<tr>
<td>cough frequency</td>
<td>(p &lt; .001)</td>
</tr>
<tr>
<td>cough severity</td>
<td>(p=.006)</td>
</tr>
<tr>
<td>severity of congestion</td>
<td>(p=.01)</td>
</tr>
<tr>
<td>severity of rhinorrhea</td>
<td>NS</td>
</tr>
<tr>
<td>child’s ability to sleep</td>
<td>(p &lt; .001)</td>
</tr>
<tr>
<td>parent’s ability to sleep</td>
<td>(p &lt; .001)</td>
</tr>
<tr>
<td><strong>combined symptom score</strong></td>
<td>6.1 (p &lt; .001) [out of 42]</td>
</tr>
</tbody>
</table>

- There were no statistically significant differences between petrolatum & no treatment for any outcome.
- Vapor rub was superior to no treatment for all symptoms, except rhinorrhea.
- Vapor rub was better than petrolatum for mostly the sleep-related outcomes.

**Considerations:**
- Mild irritant adverse effect (i.e., burning of skin, eyes, nose) present in VR-treated children only. ~15-30%
- Majority of parents (85-100%) were able to correctly guess their child’s treatment assignment (i.e. loss of blinding!)
- 9% of parents in the no-xt group admitting to giving their child a cough & cold product during the night. (1.2% petro, 7% VR, 0% no-xt)
- Children in the petrolatum group received acetaminophen more commonly by their parents. (1.2% petro, 7% VR, 0% no-xt)
- Study population did not include children under age 2. [Non-medicated product in Canada called VICKS BABY RUB (contains aloe vera and fragrances such as lavender). Labeled for use in >3 months of age - no evidence to support effectiveness.]

**Safety:**
- Serious adverse events associated with topical VR products are rare. There are case reports of vomiting and seizures in young children after accidental oral ingestion. Approximately 20 mL (4 tsp) of VR is a potentially fatal dose if ingested by a child.
- Labeled instructions warn: do not use in children < 2 yrs and do not apply the product in or under the nostrils (case report of respiratory distress in an 18 mo. old who had VR applied under her nose). An animal study suggests that VR may lead to obstruction of small nasal airways in young children.

**AE - adverse effects, URI - upper respiratory tract infection, sx - symptoms, hx - history, OTC - over-the-counter, Rx - prescription, VR - vapor rub, oint - ointment, < hs - before bedtime, tx - treatment, petro - petrolatum, NS - non significant.**

For References & Editorial Comments, see page 2.
Editorial Reviewer Comments:
- This study lacked a pre-defined clinically important symptom improvement measure, (i.e. a specific observed change in the Likert scale that translates into a clinically important outcome). Results were statistically significant but difficult to extrapolate to clinical context. The study authors emphasize the most profound effects were for the outcomes related to sleep and that the benefit is clear. What does a 1.3 difference in Likert scores (2.5 change, VR vs. 1.2 change, no-tx) actually mean with regards to improved sleep for a child?
- In general, the Health Canada restrictions on the use of OTC cough & cold products in children < 6 years of age exist because of potential harm and poor evidence of benefit. Questionable clinical benefit found with topical application of vapor rub is unlikely to "out play" the effects of oral decongestants, antihistamines and anti-tussives. [Note: no direct comparison of VR to oral treatments is available.]
- Given the safety concerns with camphor, a study examining the symptomatic benefits of a vapor rub with just menthol and eucalyptus oil could be of interest.

References:
5) Ruha AM, Graeme KA, and Field A. Late seizure following ingestion of Vicks Vaporub. Acad Emerg Med 2003; 10(6): 691.