

TRIAL: Vapor Rub, Petrolatum and No Treatment for Children with Nocturnal Cough and Cold Symptoms¹

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 given 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 restrictions² 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:

- o Partially double-blinded, randomized, single-night study design with 138 children, stratified by age (mean 5.8 ± 2.8 yrs).
- o **Included:** ages 2 to 5 yrs and 6 to 11 yrs, with URI sx of cough, congestion and rhinorrhea lasting 7 days or longer.
- o **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.
- o Acceptable routine care included: hydration, saline nasal spray not within 1 hr hs or throughout night, and use of acetaminophen or ibuprofen for comfort. Parents were instructed to avoid giving their child caffeinated beverages within 4 hours <hs.
- o Surveys were administered to parents on 2 consecutive days; 7-point Likert-scale - subjective assessment of child's sx.

Study Arm	Ingredients	Dose Volume	Parental Blinding <small>{high potential for bias}</small>
VR <small>ointment</small> e.g. VICKS VAPORUB n=44	4.8% camphor, 2.6% menthol, and 1.2% eucalyptus oil	5 mL (2-5 yrs)	parent given cup filled with VR; 30 min < hs parent applied VR below their nose prior to opening child's tx cup; child & family asked not to comment on tx odour
Petrolatum <small>ointment</small> n=47	100% pure white petrolatum jelly	10 mL (6-11 yrs)	
No Treatment, n=47	investigator blinded: all grps received an opaque bag with tx cups inside; cohort <i>unblinded</i>		

*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]

Nocturnal URI Symptoms	Statistically significant differences for between-night 7-Point Likert scale changes <small>*values estimated from Fig. 2</small>		
	VR vs. no-tx	VR vs. petrolatum	no-tx vs. petrolatum
cough frequency	1.4 (p < .001)	NS [VR marginally better, p=.07]	NS [petro marginally better, p=.09]
cough severity	0.9 (p= .006)	NS [VR marginally better, p=.06]	NS
severity of congestion	1.1 (p= .01)	NS	NS
severity of rhinorrhea	NS	NS	NS
child's ability to sleep	1.3 (p < .001)	0.9 (p = .006)	NS
parent's ability to sleep	1.6 (p < .001)	1.0 (p = .008)	NS
combined symptom score	6.1 (p < .001) [out of 42]	4.1 (p = .03) [out of 42]	NS [petro marginally better, p=.08]

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

Considerations:

- o Mild irritant adverse effect (i.e., burning of skin, eyes, nose) present in VR-treated children only. ~15-30%
- o Majority of parents (85-100%) were able to correctly guess their child's treatment assignment (i.e. loss of blinding!)
- o 9% of parents in the no-tx group admitted to giving their child a cough & cold product during the night.
- o Children in the petrolatum group received acetaminophen more commonly by their parents. (13% petro, 7% VR, 0% no-tx)
- o Study population did not include children under age 2. [Non-medicated product in Canada called **VICKS BABY RUB**³ (contains aloe vera and fragrances such as lavender). Labeled for use in > 3months of age - no evidence to support effectiveness.]

Safety:

- o 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.**⁷
- o Labeled instructions warn: do not use in children < 2 yrs and do not to 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).⁸ An *animal* study suggests that VR may lead to obstruction of small nasal airways in young children.⁹ [Detailed safety review: "Vicks VapoRub Safety and Children". Pharmacist's Letter. March 2009. Vol 25 No 250306.]

Editorial Reviewer Comments:

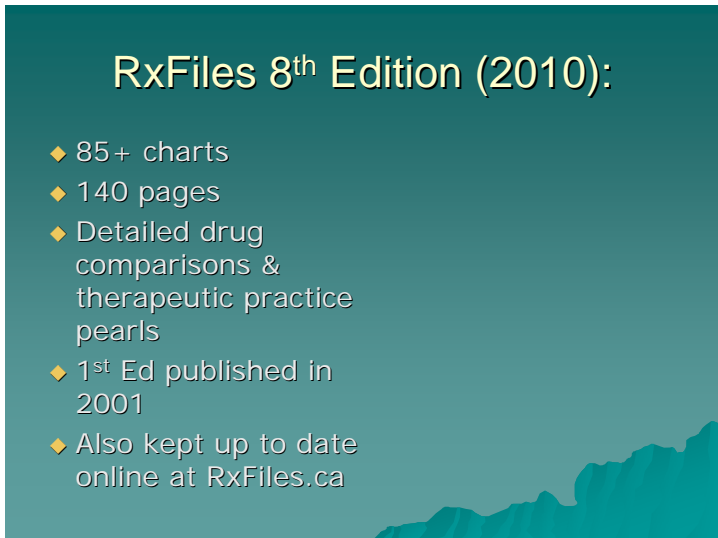
- o This study lacked a pre-defined clinically important symptom improvement measure, (i.e. a specific observed change in the Likert scale that translates into a clinically important outcome). Results were statistically significant but difficult to extrapolate to clinical context. The study authors emphasize 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?
- o 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.]
- o 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:

- 1) Paul IM, Beiler JS, King TS, et al. Vapor Rub, Petrolatum, and No Treatment for Children with Nocturnal Cough and Cold Symptoms. *Pediatrics* 2010;126(6):1-8. Funded by: Procter & Gamble Company.
- 2) Health Canada. Cough and Cold Medicine for Children. Available from: <http://www.hc-sc.gc.ca/dhp-mps/medeff/res/cough-toux-eng.php>. Accessed on: April 7, 2011.
- 3) Vicks BabyRub. Available from: <http://www.vicks.ca/en/babyrub.php>. Accessed on: April 8, 2011.
- 4) Z Flaman, S Pellechia-Clarke, B Bailey, et al. Unintentional exposure of young children to camphor and eucalyptus oils. *Paediatr Child Health* 2001;6(2):80-83.
- 5) Ruha AM, Graeme KA, and Field A. Late seizure following ingestion of Vicks VapoRub. *Acad Emerg Med* 2003; 10(6): 691.
- 6) Manoguerra AS, Erdman AR, Wax PM, et al. Camphor Poisoning: An Evidence-Based Practice Guideline for Out-of-Hospital Management. *Clinical Toxicology* 2006; 44: 357-370.
- 7) American Academy of Pediatrics. Committee on Drugs. Camphor Revisited: Focus on Toxicity. *Pediatrics* 1994; 94(1); 127-8.
- 8) American College of Chest Physicians. Misuse of Vicks VapoRub may harm infants and toddlers: toddler in respiratory distress after popular salve used. Available from: <http://www.chestnet.org/accp/article/misuse-vicks%2%AE-vaporub%2%AE-may-harm-infants-and-toddlers>. Accessed April 10, 2011.
- 9) Abanses JC, Arima S, Rubin BK. Vicks VapoRub induces mucin secretion, decreases ciliary beat frequency, and increases tracheal mucus transport in the ferret trachea. *Chest* 2009; 135: 143-8.

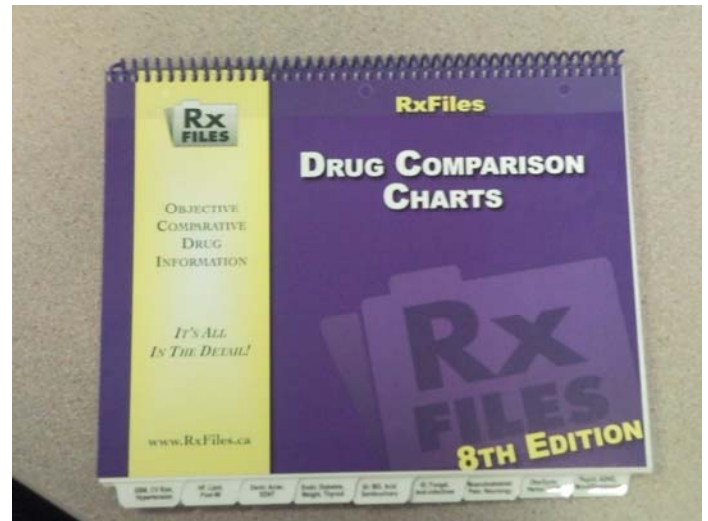
We would like to acknowledge those who contributed to the review of this document. Dr. J. Taylor, B. Jensen, L. Regier.
 Copyright 2011 RxFiles, Saskatoon Health Region: All Rights Reserved. DISCLAIMER: The content of this newsletter represents the research, experience and opinions of the authors and not those of the Board or Administration of SHR. Neither the authors nor SHR nor any other party who has been involved in the preparation or publication of this work warrants or represents that the information contained herein is accurate or complete, and they are not responsible for any errors or omissions or for the result obtained from the use of such information. Any use of the newsletter will imply acknowledgment of this disclaimer and release any responsibility of SHR, its employees, servants or agents. Readers are encouraged to confirm the information contained herein with other sources.

RxFiles Drug Comparison Charts - 8th Edition Book: See www.RxFiles.ca



RxFiles 8th Edition (2010):

- ◆ 85+ charts
- ◆ 140 pages
- ◆ Detailed drug comparisons & therapeutic practice pearls
- ◆ 1st Ed published in 2001
- ◆ Also kept up to date online at RxFiles.ca



RxFiles - Drug Comparison Charts - 8th Edition

Evidence Based Medicine (EBM) Overview	1	Sexual & Other Abuse/Injury Chart: See also OTC First Aid Chart	88
CARDIOLOGY - For CVD Risk Assessment Tool: Cardiovascular	1	Opioids Chart	70
Anti-hypertensives	2	Overseas Treatment Chart	New
ACE Inhibitor & ARB Chart	2	Painful Pain Treatment Considerations	72-73
Beta Blocker Chart	3	Seasonal Affective Disorder (SAD) Chart	74
Calcium Channel Blocker Chart	4	NEUROLOGY	
Diuretic & Misc. Anti-hypertensives Chart	5	Alzheimer's/Dementia Chart	75-77
Summary of Anti-hypertensives, Guidelines & Trials	6-9	Essential Tremor & Restless Leg Syndrome Chart	78
Antiplatelet & Antithrombotic Chart	10-11	Migraine: Acute & Prophylaxis Chart	80-81
Heart Failure	12-13	Multiple Sclerosis	79
Lipid Lowering Agents Chart	14	Parkinson's Treatment Chart	82-83
Lipid Lowering Agents Chart	15	Seizures: Antiepileptic Chart	84-85
MI Post MI Chart	16	OB/GYN & GYN	
QT Prolongation and Torsades de Pointes Chart	17	Contraception	
DERMATOLOGY		Oral Contraceptive (COC's) Chart	86-87
Various OTC (See Also: Fungal, Dermatitis, Psoriasis, Hair Loss & Head Lice Chart)	18-19	Other Hormonal Birth Control (non-COC) Chart	88
Acne Treatment Chart	18-19	Menopausal	89
Topical Corticosteroid Chart	20	Postmenopausal Herbal Therapy Chart	90
ENT (Ear-Nose-Throat) - Various OTC (Cough, Cold & Allergy Chart)	21	Postmenopausal Therapy Chart	90
Glaucoma (Topical Treatment) Chart	21	OVER THE COUNTER (OTC) & HERBAL MEDICATIONS	91
Intranasal Corticosteroid Chart	22	Cold, C, Coughs & Larynx/Throat Products	92-93
ENDOCRINE & METABOLIC		Herbal Drug Interactions Chart	94
Anti-diabetic: Insulin Replacement Chart	23	OTC - Coughs, Cough, Cold, Allergy	95
Diabetes: Antihyperglycemic (Oral Hypoglycemic) Chart	24-25	GI: Dyspepsia, Constipation & Diarrhea, Pain relief	96
Glucose Self-Monitoring (SMBG) Tips - New	26	Allerg: Fungal, Dermatitis	96
Insulin Delivery Devices: Pens - New	27	Plantar Warts, Head Lice & Vitamins	97
Insulin Management Chart & Critical Tips	28-29	PSYCHIATRY	
Landmark & Diabetes Prevention Trials	30	ADHD	98-99
Obesity: Weight Loss Drug Chart	31	Anxiety Disorders	100
Thyroid: Weight & Hypertension Chart	32-33	Antipsychotic Chart	100
GASTROINTESTINAL	34-35	Benzodiazepines Chart	102-103
Crohn's & Ulcerative Colitis Chart	37-39	Bipolar Disorder: Mood Stabilizer Chart	103-105
GERD & Peptic Ulcer Disease: Evidence & Chart	40-41	Depression	104-105
H. Pylori Therapy Chart	42	Antidepressant Chart	106
Intestinal Bowel Syndrome	43	Antidysrhythmic Drug Interaction Chart	108
Nausea & Vomiting Symptom Management	44-45	Hypertensivity Treatment Options Chart	108-109
Various OTC (GI: Dyspepsia, Constipation, Diarrhea Chart)	46	Schizophrenia: Antipsychotics Chart	110-111
GENITOURINARY - Erectile Dysfunction Chart	46	Sleep Disorders: Sedatives Chart	112-113
Sexual Dysfunction Chart	47	RESPIRATORY	
Urinary Incontinence Chart	48-49	Asthma Drug Chart	114
INFECTIOUS DISEASE		Asthma Inhalational Devices Chart	115
Adult Vaccines Chart	New	SMOKING CESSATION Chart	115
Antifungal Treatment Chart	New	MISCELLANEOUS	
Anti-infectives for Common Infections	New	Canadian Health Agencies & Regulatory Environment	116
Anti-infectives Oral Chart	New	Canadian Health Agencies & Regulatory Environment	117
HIV	56-59	CKD: Acute/Chronic Comparison Chart	New
Influenza Drug Chart	60	CKD: Erythropoietin Comparison Chart	New
Malware Prophylaxis/Prevention	61	CKD: Iron Replacement Chart	New
Parasitic: Community Acquired (CAP) Chart	62	Patient Safety: Medication Issues	New
Parasitic: Fungal/Serious Risk & CUEB-49 Card	63	Scholarly Practice, Academic: Detailing Overview	New
Urinary Tract Infections in Adults Chart	64	Substance Abuse Chart	124-125
MUSCULOSKELETAL & CONNECTIVE TISSUE	65	Transplantation Chart	New
Back Pain Treatment Chart & Treatment Options	66-67	INDEXES - Newletters & Q&A's	126-127
Chronic Non-Malignant Pain Drug Chart	68	Drug	128-134
Gout	69	Abbreviations & Symbols	135

Objective, Comparative Drug Information. Editors: Brent Jensen, Loren D. Pagan. See page 135 for Disclaimer/Copyright statement © www.RxFiles.ca