Rationality of the Rubs and Balms in Common cold
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Abstract
Vicks VapoRub® is universally used to relieve symptoms of cough and cold, chest congestion, rhinitis, headache without any clinical rationale for its use in the Modern Medicine. Though these remedies are well known to provide subjective relief of symptoms, the objective evidence to such use is absent. The data was obtained from the review of studies conducted on rubs and balms over the years and through net search. A host of adverse reactions to the popularly used rubs and balms was observed in various studies conducted so far, like respiratory distress, inflammation of eyes / other mucus membranes, mental status changes, psychological disturbances, hepatotoxicity, hepatic encephalopathy, contact dermatitis, chemical leucoderma and sudden seizures. Such rubs and balms have been self used extensively for over a century for symptomatic relief of upper respiratory congestion and aches. The manufacturers of similar products should conduct testing procedures alike cosmetics. It is desired that the label of such products must forewarn the consumers in detail about the possible adverse drug reactions. The use of such remedies in young children being disastrous and of questionable benefit, populations must be educated that use of such agents may be potentially dangerous.

Key Words
Rationality, Rubs, Balms, Common Cold

Introduction
The text books of rational modern medicine do not mention about use of rubs and balms in common cold and cough. The budding medics are also not taught about these in modern medicine (allopathic) medical colleges. Yet citizens continue to buy these products without prescription, over the counter (OTC) and stock them for self-use. It goes on to indicate the powerful influence of advertising that backs the marketing of these products. Because these irrational preparations are purchased, stocked and used, the manufacturers continue to produce, promote and push these to profit from irrational behavior. For some companies these products have become their leading brands. Without any covert intent, prejudice or ofence meant, the leading brand of the rubs and balms, Vicks Vaporub® (VV) has been chosen here to discuss our concerns. This does not mean any selective bias against the particular brand and absolve others. The reason for this selection is that VV is an internationally available, branded, OTC product, which is heavily advertised, most purchased and self-used to relieve the symptoms of cold. On Google search it showed 948000 results.[1] However the availability of the scientific data about its efficacy and clinical benefits still remains scarce.

The VV was the top-selling branded children's product in the cough/cold/flu/respiratory - treatment category based on category value sales as reported for the 12 months ending May 10, 2010. [2] The VV homepage explains that on its application on chest and throat, it temporarily relieves cough due to common cold and on its application on muscles and joints, it temporarily relieves minor aches and pains.[2] The VV is advised to be rubbed on the chest, throat and back, underneath loose clothing to allow the vapor to be inhaled. Alternatively, two teaspoonsfuls of VV can be dissolved in hot water for use as a steam inhalation. The manufacturer claims that the warm moisture inhaled in the steam will help liquefy and
loosen the mucus, allowing more effective clearance of the airways which can relieve cough as well as nasal congestion. The VV is not recommended for direct application in the nostril, and is contraindicated for children <2 years of age. Though this is mentioned in the fine print of product literature, it often goes unread by the parents. Severe respiratory problems have been reported in children <2 years, after the application of VV.[3]

**The Efficacy:** The VV contains four active ingredients levomenthol, eucalyptus oil, turpentine oil and camphor. Menthol is thought to be the principal ingredient for perceived decrease in congestion by stimulating trigeminal cold receptors. It binds to the TRPMA8 receptor (a temperature receptor), activating calcium channels causing calcium influx into the cell and lowering the external calcium concentration. The cold receptors respond by producing an efflux of calcium and depolarizing the membrane. The cooling sensation due to depolarization is perceived as increased airflow across the nostrils despite actual decrease in airflow. Thus VV offers no additional benefit in common cold and works by placebo effect only. [4] Though patients using VV feel relief from nasal congestion, studies have shown that actually there was increase in the nasal resistance within one minute, which persisted for 200 minutes of application. This was confirmed by exercise increased nasal airflow measured by rhinomanometry in 70% of healthy individuals out of which only 20% perceived an increase in nasal airflow. In contrast, when VV was applied in same healthy individuals, 100% reported a sensation of improved airflow while the objective rhinomanometry measurement showed no increased airflow in any person.[5,6]

**Adverse Effects:** The OTC market has wide range of formulations meant for dermal application which contain terpenes. The VV is one such product which contains many terpenes viz. eucalyptol, menthol, camphor, alpha-pinene, and beta-pinene. Limited data is available about the quantity of these compounds which penetrate into the skin. In a study the ex-vivo skin penetration kinetics of terpenes from VV was done. The short time in which saturation of the stratum corneum with the terpenes occurred and the high accumulation of the investigated terpenes in the skin layers proved that these easily penetrate and permeate the stratum corneum and that in vivo these may easily penetrate into the blood circulation which may be an important factor for occurrence of various ADRs reported with VV.[7]

**Respiratory Distress:** Recently, a case of VV induced severe respiratory distress which developed after VV was put directly under nose of an 18 month old girl has been reported. The VV induced increase in mucus secretion and disturbances in mucociliary function may be responsible for this. This was confirmed in animal model of airway inflammation using ferrets. The results showed that VV increased mucin secretion 63% over the controls and decreased the ciliary movement by 35% thus indicating that VV’s active ingredients are ciliotoxic and mildly proinflammatory, increasing mucus secretion and decreasing mucus clearance. Inflammation of airway can be especially serious in children since ducts are much narrower as compared to adults. Hence any increase in mucus or inflammation can narrow the ducts severely. Though the exact cause of this is unknown, it is proposed that neurogenic response to the VV could possibly increase mucus secretion, pulmonary vascular leakage, ciliary disturbances, as well as release inflammatory cytokines and contract bronchial smooth muscle.[8]

**Inflammation of Eyes:** Several cases of bilateral watering of eyes and blurred vision after the application of the VV over forehead, around the eyes, in and around the nose and to the rest of the face have been reported. Thus experience with VV provides additional evidence that it should not be applied around the eyes as VV may accidentally contaminate the eyes. Many cases of corneal injuries after contact with VV vapor blown through inhalers have been reported. The painful keratitis appears as a corneal problem that is likely due to chemical injury. This is possibly due to direct irritation from camphor (approximately 4.8% in VV). Also, VV contains small amounts of spirit of Turpentine, the vapor of which has been reported as a corneal irritant.[9,10]

**Mental Status Changes:** The VV abuse induced long term personality change, paranoid psychosis of several months duration, and acute delirium have been reported. All the psychological disturbances resolved after withdrawal of VV.[11]

**Hepatotoxicity:** A case of severe hepatotoxicity in two month old baby girl has been reported after her mother applied generous amount of VV to the baby’s chest and neck, three times a day for five days.

Camphor content of VV can cross the skin, mucous membrane, and the placental barrier, and cause significant hepatotoxicity. Ingestion of even small dose of camphor can cause fatal poisoning in young children. Hepatotoxicity may range from a mild elevation of liver function test values to hepatic encephalopathy. Since VV contains 4.8% camphor, large amounts are needed to cause toxicity. Though incidence of hepatotoxicity is very low and fatalities rare, toxicity continues to be a problem.[12]

**Other Health Hazards:** Camphor oil, a cyclic terpene with ketone structure, is derived from the Cinnamomum camphora tree. The VV contains 4.8% of camphor. Therefore, ingestion of even small amounts of such products may result in toxicity. In addition to the oral route, camphor toxicity has occurred from ingestion of nasally instilled drops and inhalation, dermal and
The major toxicity of camphor is central nervous system stimulation leading to sudden seizures. In a patient series, 9 of 19 children experienced a seizure within 4 to 120 minutes after ingesting 0.7 to 6.0 g of camphor. Increased muscular excitability may precede or follow the seizures. Acute camphor poisoning has been reported with frequent use of camphorated nasal drops in nasal congestion. Academy of Pediatrics recommends that camphor containing products should not be used in children.\textsuperscript{[14,15]} Use of topical/inhalant products containing camphor or menthol near a flame, in hot water, or in a microwave oven may cause the products to splatter and cause serious burns to the user. Therefore US FDA has included a warning about this in the monograph for all such OTC medicines.\textsuperscript{[16]} Many ingredients in the VV can cause contact dermatitis and several cases of contact dermatitis, and chemical leukoderma have been reported.\textsuperscript{[8,17,18]}

Conclusion

Among the various rubs and balms available internationally, the Vicks Vaporub\textsuperscript{®} has been self used extensively for more than a century for symptomatic relief in upper respiratory congestion and even minor aches. Many such products are also selling in India. It would be service to the humanity if manufacturers of such products conduct testing procedures alike the cosmetics. It is desired that the label of such products must forewarn the consumers in detail about the possible ADRs. The use of cold remedies in young children being of questionable benefit, populations must be educated that use of such agents may be potentially dangerous. The package inserts of camphor containing cold remedies must include the information prominently, in readable font, in vernacular language, that these should not be used in children under two years of age. All advertisements of such products must warn about the potential toxicity to the general public.\textsuperscript{[19]} Health professionals should be aware of the toxicity of such products and take proactive approach to warn their clientele about their potential dangers. The products being available online now\textsuperscript{[20]} and many off-label uses of VV are also being proposed.\textsuperscript{[21]} It remains to be seen whether the decision makers and regulatory authorities of the country would still like to continue allowing such products to be sold OTC in India.

References