Nanoparticle Emulsion Speeds Cold Sore Healing

BY MIRIAM E. TUCKER
Senior Writer

WASHINGTON — A novel topical antiviral nanoemulsion reduced the time to healing of cold sores by more than 1 day in a phase IIB study of patients with recurrent herpes labialis.

The lotion, called NB-001, is an oil-in-water emulsion containing nanometer-size droplets that permeate the skin and fuse with the herpes virus, thereby disrupting its outer surface and lysing it, without irritating normal skin. The physical mechanism of action makes drug resistance unlikely, Dr. Mary R. Flack said at the jointly held annual Interscience Conference on Antimicrobial Agents and Chemotherapy and the annual meeting of the Infectious Diseases Society of America.

The 1-day benefit seen with NB-001 is similar to that seen with oral antiviral drugs such as famciclovir and valacyclovir, available only by prescription because the Food and Drug Administration is concerned about drug resistance. Prescription and over-the-counter topical antivirals, such as docosanol, acyclovir, and penciclovir, speed healing by about half a day.

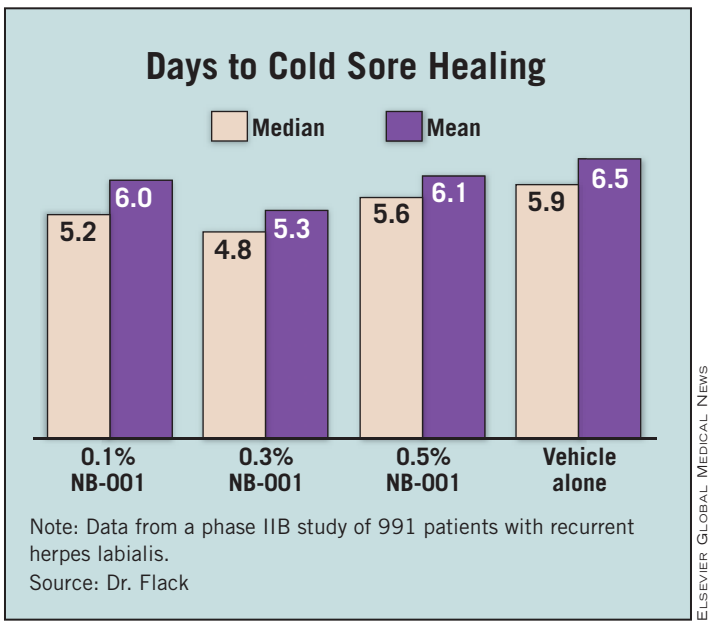
"We need a topical product that is as effective as the orals. Nanoemulsion could provide such a product," said Dr. Flack, vice president of clinical affairs at NanoBio Corp., Ann Arbor, Mich.

In a 28-center, double-blind, vehicle-controlled trial conducted by the company, 991 patients with a history of at least three cold sores per year were randomized to receive either vehicle alone or NB-001 in concentrations of 0.1%, 0.3%, or 0.5%. At symptom onset, patients began treatment five times daily until the lesion healed, or a maximum of 4 days. Of 484 patients who had an outbreak during the 6-month study, 482 received at least one dose of study medication. Of those, 92% started treatment within 4 hours of symptom onset at the prodrome or erythema stage.

The 482 patients in the intent-to-treat population had a mean age of 44 years, 71% were women, and 94% were white. Both median and mean times to healing for the group that received 0.3% NB-001 were a day or more improved, vs. vehicle alone. The group receiving 0.1% NB-001 healed about half a day faster, which was not statistically significant but was similar to the benefit seen with current topical antivirals.

The 0.5% concentration, in contrast, did not significantly reduce time to healing. At concentrations greater than 0.3%, there was precipitation of one ingredient that formed crystals, preventing permeation of the drug. This is a common phenomenon with topical agents, Dr. Flack said.

None of the subjects had drug-related skin irritation. Only negligible levels of plasma cetylpyridinium chloride (a marker for nanodroplet delivery) were seen in both treated and vehicle subjects, indicating no systemic exposure, she said. ■



Note: Data from a phase IIB study of 991 patients with recurrent herpes labialis.
Source: Dr. Flack

ELSEVIER GLOBAL MEDICAL NEWS

Adult Immunization Schedule Updated, Released for 2009

BY MIRIAM E. TUCKER
Senior Writer

This year's Adult Immunization Schedule includes the 2008 recommendation to use the pneumococcal polysaccharide vaccine in cigarette smokers and patients with asthma.

No new vaccines have been added to the schedule, but there are several changes to the chart's format, as well as updated footnotes for certain vaccines, said Dr. Gina Mootrey of the CDC's Immunization Services Administration, and her associates.

The schedule, published in January, was approved by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) and endorsed by the American College of Physicians, the American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists (MMWR 2009;57:Q1-4).

ACIP voted to recommend pneumococcal polysaccharide vaccine to adults with asthma in June 2008, based on data suggesting that adults with asthma were at more than double the risk (adjusted odds ratio 2.4) for invasive pneumococcal disease (INTERNAL MEDICINE NEWS, July 15, 2008, p. 1). The ACIP decision on smokers was made in October 2008, based on data that smoking is the strongest independent risk factor for pneumococcal disease in nonelderly immunocompetent adults, with an adjusted odds ratio of 4.1 (INTERNAL MEDICINE NEWS, Nov. 15, 2008, p. 1).

In an editorial, Dr. Gregory A. Poland and Dr. William Schaffner noted that most asthmatic adults who develop invasive pneumococcal disease already have another condition for which the vaccine is indicated, but they don't receive it (Ann. Intern. Med. 2009;150:53-6).

"Making asthma an indication for pneumococcal vaccination will resolve previous ambiguity, be consistent with the influenza vaccine recommendations, and challenge us to identify and vaccinate these patients," said Dr. Poland of the Mayo Clinic, Rochester, Minn., and Dr. Schaffner of Vanderbilt University, Nashville, Tenn.

It is now recommended that all children from 5 years through 18 years of age (in addition to children aged 6 months to 5 years, as previously recommended), receive the influenza vaccine, as well as individuals who live with or care for people at increased risk for influenza-related complications, including all health care workers.

Other changes and clarifications in the footnotes of the 2009 schedule include the following:

► A note was added to say that health care personnel are not at increased risk for human papillomavirus through occupational exposure, and that they should receive the vaccine consistent with age-based recommendations.

► A second dose of varicella vaccine should be given to adults who previously received only one dose.

► Information was added about an alternative four-dose schedule for the combined hepatitis A/B vaccine.

► The 5-year revaccination interval for the meningococcal vaccine was clarified.

Dr. Poland and Dr. Schaffner both disclosed financial ties to several vaccine manufacturers. Members of ACIP who disclosed relationships with vaccine manufacturers were not allowed to vote on issues pertaining to those companies' products. ■

The Adult Immunization Schedule is available at www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm. Statements on specific vaccines are available at www.cdc.gov/vaccines/pubs/acip-list.com. Instructions for reporting adverse events are available at www.vaers.hhs.gov or by calling 800-822-7967.

Fluids, Rest, OTC Medicines Remain Top Cold Care Choices

BY HEIDI SPLETE
Senior Writer

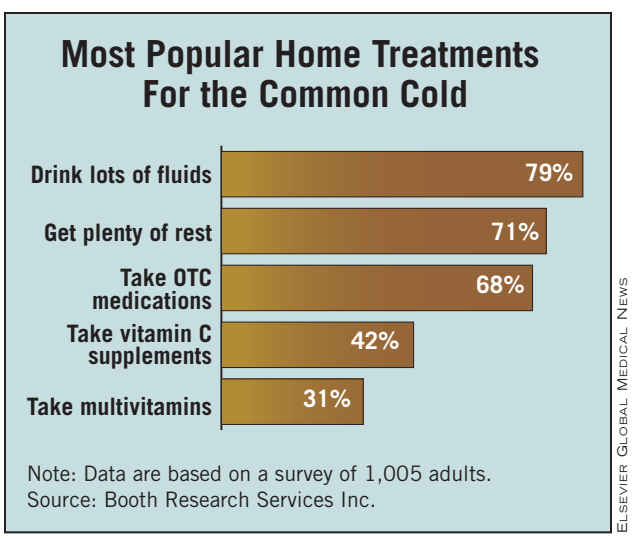
ARLINGTON, VA. — Despite the lack of evidence that over-the-counter cold medicines cure the common cold, nearly two-thirds of American adults choose them to treat symptoms, according to survey results from 1,005 individuals aged 18 and older.

The findings suggest that physicians should continue to educate patients about the limits of nonproven OTC medications and natural remedies for cold prevention and treatment, wrote Dr. Mark Moyad and his colleagues in a poster presented at the annual meeting of the American College of Nutrition.

However, Americans appear to be getting the message about hand hygiene. Overall, 72% of the survey respondents reported frequent handwashing as a first line of defense against cold prevention. Other prevention methods included taking multivitamins (48%), getting plenty of rest (41%), and taking vitamin C supplements (36%).

Once they had developed a cold, 79% of the survey respondents reported drinking lots of fluids, 71% reported getting plenty of rest, and 68% reported using OTC medications.

Data for this study were culled from a nationwide sample of respondents to an online survey conducted as part of a larger research project on the common cold in America that was commissioned by U.S. Nutrition and conducted by Booth Research Services Inc. of Atlanta. Dr. Moyad, of the University of Michigan, Ann Arbor, is on the advisory board of Zila Pharmaceuticals, the manufacturer of the vitamin C supplement Ester-C. ■



Note: Data are based on a survey of 1,005 adults.
Source: Booth Research Services Inc.

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