

Is Gonorrhea Add-On to Chlamydia Test of Benefit?

BY DAMIAN McNAMARA
Miami Bureau

JACKSONVILLE, FLA. — A majority of privately insured women tested for chlamydia are also checked for gonorrhea, which may be unnecessary given its significantly lower incidence, according to a study presented at a conference on STD prevention sponsored by the Centers for Disease Control and Prevention.

“Gonorrhea is much more rare.

Chlamydia incidence is 5%-7% versus less than 1% for gonorrhea,” Thomas L. Gift, Ph.D., said in an interview at his poster presentation.

Screening of all sexually active adolescents and females 25 years or younger for chlamydia is recommended by the CDC. However, screening for gonorrhea is only recommended for those at high risk of sexually transmitted diseases.

Dr. Gift and his associate Michele K. Bohm identified 61,183 females aged 15-

65 years who were tested for chlamydia, gonorrhea, or both in 2001. They searched outpatient claims in the Medstat Marketscan Database of approximately 4 million privately insured patients. They looked for current procedure terminology codes specific to chlamydia testing or gonorrhea testing. DNA direct or amplified dual-assay codes were also included in the study.

Patients were tested for chlamydia on 66,070 occasions and for gonorrhea on

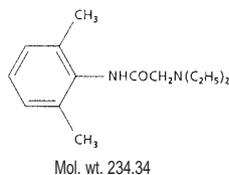
58,163 occasions. They were tested for both chlamydia and gonorrhea on 56,371 of these occasions, suggesting frequent use of dual testing assays. “Eighty-five percent of the time we found a gonorrhea test on the same day on the chart as the chlamydia test,” said Dr. Gift, an economist in the division of STD prevention at the CDC.

“There are a lot of people being tested for gonorrhea when they shouldn't be,” Dr. Gift said.

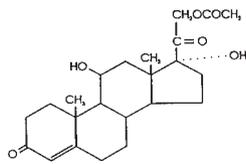
The costs can be more than economic—there are false-positive concerns with sexually transmitted infections (STIs), Dr. Gift said. “There is such a host of undefinable costs—for example, an STD diagnosis in a monogamous relationship. The prudent thing is to treat just in case, but there is wreckage strewn around by suggesting someone has an STI.”

Rx Only AnaMantle HC® 2.5% (Lidocaine HCl 3%-Hydrocortisone Acetate 2.5%) GEL

DESCRIPTION: Contains lidocaine hydrochloride 3% and hydrocortisone acetate 2.5% microdispersed in an AcidMantle vehicle. Lidocaine is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl), and has the following structure:



Hydrocortisone acetate has a chemical name pregn-4-ene-3, 20-dione, 21-(acetyloxy)-11,17-dihydroxy-(11 β). It has the following structural formula:



Each gram of AnaMantle HC® 2.5% Gel contains lidocaine hydrochloride 30 mg and hydrocortisone acetate 25 mg. Inactive ingredients include aluminum sulfate, calcium acetate, carbomer, cetyl alcohol, citric acid, glycerin, methylparaben, mineral oil, petrolatum, polycarbophil, polysorbate 60, propylene glycol, propylparaben, purified water, sodium citrate, sodium hydroxide, sorbitan stearate, stearic acid, stearyl alcohol and urea.

CLINICAL PHARMACOLOGY:

MECHANISM OF ACTION: AnaMantle HC® 2.5% Gel releases lidocaine from an AcidMantle vehicle to stabilize the neuronal membrane by inhibiting the ionic fluxes required for initiation and conduction of impulses, thereby effecting local anesthetic action. Hydrocortisone acetate provides relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. AcidMantle base can help maintain the pH balance of the skin.

PHARMACOKINETICS: Lidocaine may be absorbed following topical administration to mucous membranes, its rate and extent of absorption depending upon the specific site of application, duration of exposure, concentration, and total dosage. In general, the rate of absorption of local anesthetic agents following topical application occurs most rapidly after intratracheal administration. Lidocaine is also well-absorbed from the gastrointestinal tract, but little intact drug appears in the circulation because of biotransformation in the liver.

Lidocaine is metabolized rapidly by the liver, and metabolites and unchanged drug are excreted by the kidneys. Biotransformation includes oxidative N-dealkylation, ring hydroxylation, cleavage of the amide linkage, and conjugation. N-dealkylation, a major pathway of biotransformation, yields the metabolites monoethylglycinexylidide and glycinexylidide. The pharmacological/toxicological actions of these metabolites are similar to, but less potent than, those of lidocaine. Approximately 90% of lidocaine administered is excreted in the form of various metabolites, and less than 10% is excreted unchanged. The primary metabolite in urine is a conjugate of 4-hydroxy-2, 6-dimethylaniline.

The plasma binding of lidocaine is dependent on drug concentration, and the fraction bound decreases with increasing concentration. At concentrations of 1 to 4 g of free base per mL, 60 to 80 percent of lidocaine is protein bound. Binding is also dependent on the plasma concentration of the alpha-1-acid glycoprotein.

Lidocaine crosses the blood-brain and placental barriers, presumably by passive diffusion.

Studies of lidocaine metabolism following intravenous bolus injections have shown that the elimination half-life of this agent is typically 1.5 to 2 hours. Because of the rapid rate at which lidocaine is metabolized, any condition that affects liver function may alter lidocaine kinetics. The half-life may be prolonged two-fold or more in patients with liver dysfunction. Renal dysfunction does not affect lidocaine kinetics but may increase the accumulation of metabolites.

Factors such as acidosis and the use of CNS stimulants and depressants affect the CNS levels of lidocaine required to produce overt systemic effects. Objective adverse manifestations become increasingly apparent with increasing venous plasma levels above 6 g free base per mL. In the rhesus monkey arterial blood levels of 18-21 g/mL have been shown to be threshold for convulsive activity.

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses.

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma protein in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS: AnaMantle HC® 2.5% Gel is used for the anti-inflammatory and anesthetic relief of itching, pain, soreness and discomfort due to hemorrhoids, anal fissures, pruritus ani and similar conditions of the anal area.

CONTRAINDICATIONS: AnaMantle HC® 2.5% Gel should not be used in patients with a history of sensitivity to any of its ingredients or adverse reactions to lidocaine or amide anesthetics, which usually do not cross-react with "caine" ester type anesthetics. If excessive irritation and significant worsening occur, discontinue use and seek the advice of your physician. AnaMantle HC® 2.5% Gel and topical lidocaine should be used cautiously in those with impaired liver function, as well as the very ill or very elderly and those with significant liver disease. AnaMantle HC® 2.5% Gel should be used with caution in patients receiving antiarrhythmic drugs of Class I since the adverse effects are additive and generally synergistic. AnaMantle HC® 2.5% Gel is contraindicated for tuberculous or fungal lesions or skin vaccination, varicella and acute herpes simplex. Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

WARNINGS: For external use only. Not for ophthalmic use. Product could harm small children if chewed or swallowed. Individual tubes are NOT child resistant. Keep the product inside the child resistant blister until ready to use.

Keep product and cleansing wipes out of the reach of children.

Topical formulations of lidocaine may be absorbed to a greater extent through mucous membranes and abraded, fissured or irritated skin than through intact skin. AnaMantle HC® 2.5% Gel should not be ingested or applied into the mouth, inside of the nose or in the eyes. AnaMantle HC® 2.5% Gel should not be used in the ears. Any situation where lidocaine penetrates beyond the tympanic membrane into the middle ear is contraindicated because of ototoxicity associated with lidocaine observed in animals when instilled in the middle ear. AnaMantle HC® 2.5% Gel should not come into contact with the eye or be applied into the eye because of the risk of severe eye irritation and the loss of eye surface sensation which reduces protective reflexes and can lead to corneal irritation and possibly abrasion. If eye contact occurs, rinse out the eye immediately with saline or water and protect the eye surface until sensation is restored.

PRECAUTIONS: If irritation or sensitivity occurs or infection appears, discontinue use and institute appropriate therapy. If extensive areas are treated, the possibility of systemic absorption exists. Systemic absorption of topical steroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glycosuria in some patients. Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Therefore, patients receiving a large dose of potent topical steroids applied to a large surface area, or under an occlusive dressing, should be evaluated periodically for evidence of HPA axis suppression. If noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Recovery of the HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Children may absorb proportionately larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. If irritation develops, topical steroids should be discontinued and appropriate therapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Studies of lidocaine in animals to evaluate the carcinogenic and mutagenic potential of the effect on fertility have not been conducted.

Use in Pregnancy: Teratogenic Effects: Pregnancy Category C. Reproduction studies have been performed for lidocaine in rats at doses up to 6.6 times the human dose and have revealed no evidence of harm to the fetus caused by lidocaine. There are, however, no adequate and well-controlled studies in pregnant women. Animal reproduction studies are not always predictive of human response. General consideration should be given to this fact before administering lidocaine to women of childbearing potential, especially during early pregnancy when maximum organogenesis takes place.

Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this drug is administered to a nursing mother.

Pediatric Use: Safety and efficacy in children have not been established.

ADVERSE REACTIONS: During or immediately following application of AnaMantle HC® 2.5% Gel, there may be transient stinging or burning from open areas of skin, or transient blanching (lightening), or erythema (redness) of the skin.

DOSAGE AND ADMINISTRATION: Clean the affected area with a single-use cleansing wipe before applying AnaMantle HC® 2.5% Gel to the affected area(s) twice daily or as directed by a physician. Remove the cap from the single-use tube. While holding the tube, squeeze the tube to fill the applicator until a small amount of gel shows and lubricate the end of the tip with gel. Gently insert the applicator tip into anal area. Continue squeezing the body of the tube as it is moved around the areas of discomfort, and lastly, around and in the anal opening (if directed by physician).

Do not completely insert the applicator and tube into the anus or insert deep into the rectum. Once application is completed, the tube with built-in applicator should be gently removed from the area and disposed. Note that an adequate amount of AnaMantle HC® 2.5% Gel for an application to the anal and peri-anal area will be applied through the applicator tip by gently squeezing the tube during application. AnaMantle HC® 2.5% Gel should not be used in excess of recommendations or for prolonged use in the anal canal. If the condition does not respond to repeated courses of AnaMantle HC® 2.5% Gel, or should worsen, discontinue use and seek the advice of your physician.

HOW SUPPLIED: AnaMantle HC® 2.5% Gel—NDC 0482-4804-20 contains 20 single-use tubes, each with a built-in applicator, 1/4 oz (7 g) and 20 single-use cleansing wipes.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Store at controlled room temperature 15°-30° C (59°-86° F).

Protect from freezing.

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Large Weight Gain Results in Highest NICU Admissions

WASHINGTON — Either too much or too little weight gain during pregnancy could increase the risk of neonatal intensive care unit admission and peripartum complications, according to data presented at the annual meeting of the American College of Obstetricians and Gynecologists.

The highest quintiles of maternal weight gain during pregnancy were significantly associated with rates of NICU admission in a study of 2,784 singleton pregnancies, Dr. Teresa Tam and her colleagues, of Saint Joseph Hospital, Chicago, reported in a poster.

After adjustment for age, delivery method, and prepregnancy weight, among other factors, the medium weight gain quintiles— 22-29 pounds and 30-35 pounds— were associated with the lowest NICU transfer rates of 3.3% and 2.6%, respectively. The study did not analyze the specific outcomes that prompted the NICU transfers.

A second poster by Dr. Devendra A. Patel of Weill Cornell Medical College, New York, and colleagues found that heavier women had almost twice the rate of maternal and fetal complications as women of normal weight.

Dr. Patel found no fetal complications and 11 peripartum complications among 68 women whose BMI was less than 30 kg/m², compared with 5 fetal complications and 20 peripartum complications among 78 women whose BMI was 30 kg/m² or higher. The measured outcomes included pregnancy-induced hypertension, diabetes, premature membrane rupture, dystocia, abruption placenta, oligohydramnios, and placenta previa. Postpartum complications included bleeding and infection, and fetal outcomes included distress, illness, and stillbirth.

An analysis of a larger sample while controlling for confounding variables is needed to confirm the study's validity, the investigators wrote.

—Heidi Splete