HEXACHLOROPHENE AND SKIN CARE OF NEWBORN INFANTS

The question of safety has been raised by the recent evidence that levels of hexachlorophene in the blood of newborn infants receiving daily baths with a 3% solution are close to levels which are neurotoxic for adult rats. Hexachlorophene is widely used in newborn nurseries, but techniques vary considerably; they range from meticulous, double, early bathing followed by daily baths, to alternate day washing with a diluted solution followed by rinsing off.

Blood levels associated with leg weakness progressing to paralysis in the adult rat with chronic oral administration have ranged from 0.985 to 1.48 p.p.m. Toxic manifestations have not been observed nor recognized in newborn infants with “meticulous” daily washing. The chemical is readily absorbed from the skin, resulting in blood levels of 0.009 to 0.646 p.p.m. The compound is excreted as a monoglucuronide in the bile and feces. Convulsions have been reported in an infant 4 days after repeated application of the 3% emulsion to the skin without subsequent rinsing; and, toxic manifestations have been observed in burn patients, but at relatively high serum levels (29 µg/ml), after denuded areas of the skin have been washed with hexachlorophene.

It is not known whether or not this substance as currently used on infants is toxic. Although the symptoms observed in adult man and adult rats are similar, the actual blood levels at which symptoms are produced in man appear to be much higher. Symptomatology in the rat with chronic oral administration was accompanied by brain lesions, cerebral edema, and cystic spaces in the white matter of the brain; these lesions were reversible over a period of 6 weeks when hexachlorophene was discontinued. Similar lesions have been produced in experimental intoxication of monkeys following both subcutaneous administration and application of hexachlorophene to the skin. The animals did not demonstrate abnormal neurological signs even with plasma levels of 3.1 µg/ml, although papilledema was found at autopsy in some instances. It is not presently known whether the lesions are reversible when hexachlorophene is discontinued.

For a number of reasons, it appears that, at this time, there is little justification on microbiological grounds for routine, daily hexachlorophene baths for the newborn infant. With the “meticulous” techniques, the rate of colonization with coagulase-positive staphylococci and the incidence of skin lesions is reduced. However, there is no documented experience where this technique has arrested a serious nursery epidemic. It is also well established that the use of hexachlorophene increases colonization with gram-negative organisms as well as the incidence of gram-negative disease. Finally, for reasons that have not been defined, the problem of serious staphylococcal disease in the nursery has not been of major importance during the last 5 years, as it was 10 to 15 years ago, whether or not hexachlorophene has been used for skin care of newborn infants.

Until further evidence is forthcoming, the Committee feels that the following warning is appropriate:

WARNING: The safety of daily bathing of infants with hexachlorophene-containing solutions has not been established. Blood levels found in newborns bathed daily in 3% hexachlorophene solutions have been shown to approach levels known to be neurotoxic in experimental animals. Therefore, the routine prophylactic use of hexachlorophene for total

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body bathing of newborn infants in hospital nurseries or at home is not recommended.

RECOMMENDATIONS

At present the Committee recommends dry skin care; washing with plain, nonmedicated soap and tap water; or washing with tap water alone for skin care of the newborn infant. It should be emphasized that the two most important factors in the transmission of infection from infant to infant are hand contact and breaks in technique. These factors can be minimized by scrupulous hand washing before entering the nursery as well as just before and just after handling each infant. An iodophor preparation, 3% hexachiorophene emulsion, or any other cleansing agent may be used.10

If an outbreak of staphylococcal disease occurs in a nursery, there should be a thorough evaluation of techniques and facilities, and if these are found to be inadequate, corrections should be made. When nursery infection is present, short term once daily prophylactic bathing of newborn infants with 3% hexachlorophene emulsion, followed by rinsing, may be considered by the physician in charge; but only as a part of a total program of control of infections.10-11

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Editor's Note: This was the position of the Academy at the time of going to press, March 13, 1972. See also page 492, this issue.

REFERENCES

5. Unpublished data made available by Winthrop Laboratories to the F.D.A.

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