Clinical Trial N Engl J Med. 1995 Mar 2;332(9):562-6. doi: 10.1056/NEJM199503023320903.

A controlled trial of povidone-iodine as prophylaxis against ophthalmia neonatorum

S J Isenberg [1], L Apt, M Wood

Affiliations

Affiliation

1 Department of Ophthalmology, Jules Stein Eye Institute, Harbor-UCLA Medical Center, UCLA School of Medicine 90024-7001.

PMID: 7838190 DOI: 10.1056/NEJM199503023320903

Free article

Abstract

Background: Neonatal conjunctivitis (ophthalmia neonatorum) continues to cause blindness because the agents used prophylactically to prevent this condition are not completely effective and are not widely available in many parts of the world. Povidone-iodine ophthalmic solution is an effective antibacterial agent with broad antibacterial and antiviral activity to which no bacteria are known to be resistant, and it is far less expensive and less toxic than the agents currently used to prevent neonatal conjunctivitis.

Methods: We conducted a masked, prospective trial involving 3117 infants born over a period of 30 months in a hospital in Kenya. Shortly after birth each infant received a 2.5 percent solution of povidone-iodine (n = 1076), a 1 percent solution of silver nitrate (n = 929), or 0.5 percent erythromycin ointment (n = 1112) in both eyes. Randomization was achieved by rotating the three medications after each was used for a week.

Results: Of the neonates treated with povidone-iodine, 13.1 percent had infectious conjunctivitis, as compared with 17.5 percent of those treated with silver nitrate ($P < 0.001$) and 15.2 percent of those treated with erythromycin ($P = 0.01$). Povidone-iodine was more effective against Chlamydia trachomatis than was silver nitrate ($P < 0.001$) or erythromycin ($P = 0.008$). There were 104 cases of noninfectious conjunctivitis (9.7 percent) in the povidone-iodine group, as compared with 129 in the silver nitrate group (13.9 percent, $P < 0.001$) and 148 in the erythromycin group (13.3 percent, $P = 0.004$). Many cases of noninfectious conjunctivitis were probably due to a toxic reaction to the treatment itself. The incidence of Neisseria gonorrhoeae and Staphylococcus aureus infections was similar in the three groups.

Conclusions: A 2.5 percent ophthalmic solution of povidone-iodine as prophylaxis against ophthalmia neonatorum is more effective than treatment with silver nitrate or erythromycin, and it is less toxic and costs less.

Comment in

Povidone-iodine to prevent ophthalmia neonatorum.

Rotta AT.

N Engl J Med. 1995 Jul 13;333(2):126; author reply 127. doi: 10.1056/NEJM199507133330212.

PMID: 7777020 No abstract available.