

Prophylaxis of ophthalmia neonatorum is not dependent entirely on the type of prophylaxis used. Host and environmental factors are as important as the prophylactic. These conclusions are reached by the investigators in the study presented here.

OPHTHALMIA NEONATORUM: EVALUATION OF DIFFERENT METHODS OF PROPHYLAXIS IN NEW YORK CITY

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THE INSTILLATION of silver nitrate in a 1 per cent solution in the eyes of newborn infants was made compulsory in New York City on August 1, 1922, but its practice had been officially urged as early as 1905.¹ The original recommendation of such prophylaxis in a 2 per cent solution was made in 1881 by Credé, in Leipzig. He stated that 226 cases of ophthalmia had occurred from 1874 to May, 1880, among 2,266 newborn infants, but that following its use in 200 infants born from June to December, 1880, none occurred.² In a later communication³ he wrote that only four cases of ophthalmia had occurred in the same hospital from 1880 to 1883 after the use of silver nitrate solution in 1,160 newborn infants. The Credé method of prophylaxis soon spread to the rest of Europe and America with the concentration of silver nitrate reduced to 1 per cent. Ophthalmia and blindness were said to have been reduced.^{1,4,5} However, this was questioned by some investigators. In London, 760 cases of ophthalmia were reported in 1915, and 617 in 1930⁶ in spite of silver nitrate prophylaxis, and in Philadelphia, Lehrfeld reported in 1935 that he found 632 cases of ophthalmia, of which 30 per cent were gonococcal,⁷ in the records

of some 28,000 newborn infants who had had silver nitrate prophylaxis. Only since the wide use of antibiotics has a marked reduction in gonococcal ophthalmia been noted (Table 1).⁴

The failure to change significantly the occurrence of ophthalmia by a single instillation of silver nitrate as a prophylactic agent,^{6,7,14,15} the harm caused by the occasional mistaken use of stronger solutions,^{7,8} the considerable local irritation caused by the drug^{4,7,9-13,15,16} and the fall of incidence in gonococcal ophthalmia after the widespread use of antibiotics (Table 1)⁴ led a number of investigators to question the value of silver nitrate prophylaxis or to advise its abandonment.^{4,6,13,16-19} The Board of Health of New York City considered the problem and amended the Sanitary Code on January 13, 1955, to permit the instillation of an effective agent in the eyes of newborn infants or the intramuscular injection of 50,000 units of penicillin as prophylactic measures against ophthalmia neonatorum. To allow greater experimentation, a subsection was added allowing the board to grant permission to hospitals to omit all prophylaxis under controlled conditions. A number of maternity services began to experiment

with various antibiotics and some omitted all prophylaxis. However, the incidence of gonorrheal ophthalmia was so low (Table 1) that an evaluation of different methods by single institutions did not yield figures significant enough for comparison. On December 5, 1956, the Board of Health repealed the section of the Sanitary Code which made prophylaxis of ophthalmia neonatorum mandatory. A review of the methods used and the results obtained by all hospitals in the city during the years 1956, 1957, and 1958 was undertaken and is the substance of this report.

Method

Data were collected from 96 hospitals giving maternity care in New York City during the three years. They were classified as 57 voluntary hospitals, which accepted private and ward patients; 15 municipal hospitals, where no private patients were received; and 24

proprietary hospitals, which accepted private patients only. The total number of births in these hospitals was 472,580, 97 per cent of the total births in the city, excluding those in federal hospitals.

The unit of observation was a newborn infant with gonorrheal ophthalmia diagnosed clinically by a purulent discharge, and bacteriologically by a positive smear or culture or both. Information was obtained from each hospital about the number of live births in the hospital in each of the years under study and their distribution by ethnic group and by type of service. These data were checked against the records in the Department of Health. The hospitals also furnished information on the type of prophylaxis, if any, that was used during the three years and the period of time during which it was used. Cases of gonococcal ophthalmia are reportable. To make certain that all were included, a physician visited the hospitals and reviewed the charts of the infants. Unreported cases were found which, added to those reported, gave a total of 49 for the three years.

Table 1—Reported Cases of Gonococcal Ophthalmia Neonatorum and Rates per 100,000 Live Births in New York City, 1942-1956

Year	Gonorrheal Ophthalmia Neonatorum	Rate per 100,000 Live Births
1942	23	17.43
1943	28	20.80
1944	46	37.49
1945	41	31.82
1946	23	15.06
1947	12	7.01
1948	8	8.06
1949	0	0.00
1950	4	2.57
1951	0	0.00
1952	1	0.61
1953	0	0.00
1954	2	1.22
1955	2	1.21
1956	3	1.81

Results

Table 2 gives the incidence rates of gonococcal ophthalmia according to the type of hospital of birth. It is striking that no cases occurred in proprietary hospitals. The rate in municipal hospitals was about four times as high as in voluntary hospitals. Table 3 gives the incidence rates of gonococcal ophthalmia according to the type of hospital service of birth. Only one case occurred on the private service compared with 48 on the ward service.

Silver Nitrate Prophylaxis

There were 17 cases of gonococcal ophthalmia among 258,621 infants who received silver nitrate prophylaxis, a rate of 6.6 per 100,000 live births. Of

Table 2—Numbers and Rates of Cases of Gonococcal Ophthalmia Neonatorum in Voluntary, Municipal and Proprietary Hospitals, According to Type of Prophylaxis Used, New York City, 1956-1958

(Rates per 100,000 Live Births)

Type of Prophylaxis	Type of Hospital											
	Voluntary			Municipal			Proprietary			Total		
	Number of Births	Cases No.	Rate	Number of Births	Cases No.	Rate	Number of Births	Cases No.	Rate	Number of Births	Cases No.	Rate
None	53,901	10	18.6	6,545	12	183.3	25,961	0	0	86,407	22	25.5
Saline	13,438	1	7.4	—	—	—	604	0	0	14,042	1	7.1
Silver nitrate 1 per cent	156,169	9	5.8	56,705	8	14.1	45,747	0	0	258,621	17	6.6
Antibiotic ointment or solution	45,623	1	2.2	28,811	8	27.8	5,877	0	0	80,311	9	11.2
Penicillin, 50,000 units, by injection	23,109	0	0	10,090	0	0	—	—	—	33,199	0	0
Total	292,190	21	7.2	102,151	28	27.4	78,189	0	0	472,580	49	10.4

these 17 cases, eight occurred in municipal hospitals among 56,705 live births, a rate of 14.1; eight occurred among 46,687 live births in ward patients of voluntary hospitals, a rate of 17.1; and one case occurred among 109,482 private patients of voluntary hospitals, a rate of 0.7. No cases occurred in proprietary hospitals.

No Prophylaxis

Twenty-two cases of gonococcal ophthalmia occurred in hospitals among 86,407 infants born alive who received no prophylaxis, a rate of 25.5 per 100,000 live births. All occurred in ward patients. The rate was 18.6 per 100,000 live births in voluntary hospitals and 183.3 in municipal hospitals. No cases occurred in proprietary hospitals or on the private services of voluntary hospitals.

Saline

Physiologic salt solution was instilled in the infants' eyes after birth in four voluntary hospitals with a total of 13,438 live births. One case of gonococcal ophthalmia occurred in a ward infant, a rate of 7.4 per 100,000 live births. No cases occurred among 12,671 infants born on the private services of these hospitals or among 604 infants so treated in proprietary hospitals.

Antibiotic Ointments and Solutions

Various types of antibiotic ointments or solutions were used in the eyes of 80,311 newborn infants. Nine cases of gonococcal ophthalmia occurred, a rate of 11.2 per 100,000 live births. Seven of these cases followed the use of bacitracin ointment in the eyes of 1,935 infants born in a municipal hospital located in a district that annually reports the highest incidence of gonorrhoea in the city. The eighth case occurred on the ward service of a voluntary hospital following the use of Ilotycin ointment as a prophylactic in the eyes of

1,503 infants. No cases developed among the 10,885 infants treated with Ilotycin ointment born on the private service of voluntary hospitals. The ninth case occurred following the use of penicillin ointment in the eyes of 19,297 infants born in a municipal hospital.

As with other methods of prophylaxis no case occurred in a proprietary hospital. The numbers and rates for the different antibiotics are given in Table 4.

Penicillin Injections

An injection of 50,000 units of penicillin was given to 23,109 infants in voluntary hospitals and 10,090 in municipal hospitals. No case of ophthalmia occurred.

Discussion

Many papers have been published on the value of antibiotics as prophylactic agents against ophthalmia neonatorum. These have compared the local instillation of a solution of 1 per cent silver nitrate with the application of an ointment or a solution of bacitracin,^{13,21,22} chlortetracycline,²³ erythromycin,¹¹ oxytetracycline^{12,17} or penicillin,^{8-10,13,15,24-26} or with the intramuscular injection of 50,000 units of penicillin.^{15,25,27} Several of the reports indicated a failure of silver nitrate as a prophylactic measure against gonococcal ophthalmia.^{7,10,14,15,22,27} In many of the trials, gonococcal ophthalmia did not occur with either method. What was measured was the incidence of nonspecific purulent discharge from the eyes, and silver nitrate appeared to be the greater offender. However, the importance of prophylaxis is to prevent serious eye lesions and blindness, and these are caused by the gonococcus.¹⁸ Most of the reports dealt with small numbers and, usually, with selected population groups.

Table 3—Numbers and Rates of Cases of Gonococcal Ophthalmia Neonatorum According to Type of Hospital Service and Type of Prophylaxis Used, New York City, 1956-1958

(Rates per 100,000 Live Births)

Type of Prophylaxis	Ward Service						Private Service							
	Municipal		Voluntary		Total Ward Service		Voluntary	Pro- prietary	Total Private Service					
	Number of Births	Cases No.	Number of Births	Cases No.	Number of Births	Cases No.				Number of Births	Number of Births	Cases No.		
							Rate	Rate	Rate					
None	6,545	12	188.3	11,571	10	86.4	18,116	22	121.4	42,330	25,961	68,291	0	0
Saline	—	—	—	767	1	130.4	767	1	130.4	12,671	604	13,275	0	0
Silver nitrate 1 per cent	56,705	8	14.1	46,687	8	17.1	103,392	16	15.5	109,482	45,747	155,229	1	0.7
Antibiotic ointment or solution	28,811	8	27.8	14,534	1	6.9	43,345	9	20.8	31,089	5,877	36,966	0	0
Penicillin, 50,000 units, by injection	10,090	0	0	5,671	0	0	15,761	0	0	17,438	—	17,438	0	0
Total	102,151	28	27.4	79,230	20	25.2	181,381	48	26.4	213,010	78,189	291,199	1	0.3

The action of the Board of Health permitted considerable experimentation in New York City, and it was possible to collect data on large enough numbers of births to make an evaluation of different methods of prophylaxis feasible, in spite of the low incidence of gonococcal ophthalmia. Unfortunately, in all but two instances, the experimental method consisted in alternating long periods of one type of prophylactic treatment with equally long periods of another type of prophylaxis. Considerable bias is introduced into this type of experiment. As the data from the various hospitals were gathered, it became apparent that in order to make a proper evaluation it was necessary to take into account not merely the agent used, but also such host and environmental factors as the type of hospital of birth, the type of service and the socioeconomic status of

the mother. For instance, it was striking that not a single case occurred among 78,000 newborn infants in proprietary hospitals, where all deliveries are made by private physicians, although the number of deliveries in such hospitals was about 16 per cent of the city total. On the other hand, 28 or 57 per cent of the cases of gonococcal ophthalmia occurred in municipal hospitals, where only ward patients were accepted, although the number of births in these hospitals, 102,000, was only 22 per cent of the total.

The bulk of deliveries occurred in voluntary hospitals, where both private and ward patients were admitted. There were about 292,000 births and 21 cases of gonococcal ophthalmia in these hospitals, a rate of 7.2 per 100,000 live births. If the classification of the cases of ophthalmia is made by type of service

Table 4—Numbers and Rates of Cases of Gonococcal Ophthalmia in Newborn Infants Treated Prophylactically with Antibiotic Ointments or Solutions, New York City 1956-1958

(Rates per 100,000 Live Births)

Antibiotic	Type* of Hospital	Births		Cases						
		White	Nonwhite	Total	White		Nonwhite		Total	
					No.	Rate	No.	Rate	No.	Rate
Achromycin	V	10,104	932	11,036	0	0	0	0	0	0
Aureomycin	M	4,007	982	4,989	0	0	0	0	0	0
Bacitracin	M	99	1,836	1,935	0	0	7	381.0	7	362.0
Chloromycetin	V	1,860	67	1,927	0	0	0	0	0	0
Ilotycin	P	3,105	389	3,494	0	0	0	0	0	0
Ilotycin	V	11,127	1,261	12,388	0	0	1	79.0	1	8.2
Neomycin	M	1,571	1,019	2,590	0	0	0	0	0	0
Neosporin	V	3,281	1,553	4,834	0	0	0	0	0	0
Penicillin	M	4,688	14,609	19,297	0	0	1	7.0	1	5.0
Penicillin	V	7,726	397	8,123	0	0	0	0	0	0
Terramycin	P	2,209	174	2,383	0	0	0	0	0	0
Terramycin	V	6,727	588	7,315	0	0	0	0	0	0
Total		56,504	23,807	80,311	0	0	9	37.8	9	11.2

* V—Voluntary; M—Municipal; P—Proprietary.

rather than by type of hospital, there was one case of gonococcal ophthalmia among approximately 291,000 newborn infants delivered by private doctors and 48 cases among about 181,000 patients on ward services. The incidence of gonococcal ophthalmia among ward patients was practically the same whether the patient was in a municipal hospital or a voluntary hospital. There were 28 cases among the 102,000 patients in municipal hospitals, a rate of 27.4 per 100,000, and 20 among the 79,000 ward patients in voluntary hospitals, a rate of 25.2 per 100,000 live births.

Similar types of hospitals had different experiences with the same method of prophylaxis, depending on the socioeconomic level of the patients they received. Of two voluntary hospitals, A drew its ward patients largely from a low socioeconomic area with one of the highest incidence rates of gonorrhea in the city; B obtained its ward patients from a low middle class area where the incidence rate of gonorrhea is considerably lower. Without any prophylaxis, four cases of gonococcal ophthalmia occurred among 1,974 infants in Hospital A, while no cases occurred among 3,288 infants who had no treatment in Hospital B.

A similar difference occurred in two municipal hospitals. Hospital C is located in and draws its patients from one of the poorest districts of the city. It is an all Negro section with poor housing and excessive crowding and has one of the worst health records in the city. In 1956-1958 the infant mortality, tuberculosis mortality, and venereal disease incidence rates were the highest of any district in the city; the gonorrheal rate was seven times higher than for the entire city. This hospital had 11,150 live births in the three years. Silver nitrate solution was used prophylactically during most of the period, but for about a year bacitracin and no prophylaxis were alternated. Cases of

gonorrheal ophthalmia occurred on all three regimes and were as follows:

Prophylactic Agent	Number of Infants	Cases	
		No.	Rate/1,000
Silver nitrate solution	7,219	2	0.28
No prophylaxis	1,996	8	4.00
Bacitracin ointment	1,935	7	3.63
Total	11,150	17	1.52

The rate of gonococcal ophthalmia following silver nitrate prophylaxis was about 93 per cent lower than the rate when no prophylaxis was used. The difference is statistically significant at the 1 per cent level. Since the patients were drawn from the same areas for the entire period, it is reasonable to assume comparable populations so far as risk is concerned. On the basis of the results obtained at this hospital, there appears to be no difference when bacitracin ointment or no prophylaxis is used.

Municipal Hospital D also caters to a low income group, but the health conditions of the district from which it draws its patients are better. The gonorrheal rate is about a fifth of that in district C. During the three years under study, 7,162 infants were born in this hospital, of whom 81 per cent were white. Silver nitrate solution was used in the eyes of 2,173 infants in 1956 and chlortetracycline ointment in the eyes of 4,989 infants in 1957 and 1958. No case of gonococcal ophthalmia occurred.

The importance of host and environmental factors in the risk of gonococcal ophthalmia is clearly seen in the fact that during the three years there were about 291,000 live births among private patients and about 181,000 among ward patients. Only one case occurred in a private patient, a rate of 0.3 per 100,000 live births, while 48 were observed in

ward patients, a rate of 26 per 100,000 or 87 times greater. In New York City, as in other urban centers, the Negro population is usually the worst housed and the poorest paid. Its health conditions are the lowest. The Puerto Rican population in New York City ranks not far above it in health conditions. Of the 49 cases of gonococcal ophthalmia, 40 occurred in Negro infants, a rate of 43.5 per 100,000 live births as compared to nine in white infants, a rate of 2.3 per 100,000. Furthermore, of these nine cases five were in Puerto Rican infants, although the number of births among Puerto Rican women was only about 15 per cent of births in white New York women.

The conclusions that appear valid from the present study and a reading of the literature are that no proper evaluation has ever been made of silver nitrate solution as a prophylactic drug against ophthalmia neonatorum. Nor has any other drug been properly evaluated. It is indeed questionable whether the single application of any drug to the eyes of an infant actually exposed to infection will invariably prevent gonococcal ophthalmia. The present study stresses the importance of host and environmental factors in the incidence of gonococcal ophthalmia. These factors have not been discussed in previous studies, so that the assumption has been that the risk of developing gonococcal ophthalmia is the same in all infants, no matter what their ethnic and socioeconomic background are.* The present study shows that the difference in risks is considerable. There is little need for prophylaxis in good economic areas.

* Unfortunately, none of the hospitals supplying data carried out any experiments to determine which of their newborns were actually exposed to gonorrhoeal infection at birth. The conclusions of the present study are hence based upon an inference concerning the population at risk drawn from what appear to be significant social and environmental data.

In poor areas, however, where the incidence of venereal disease is high, gonococcal ophthalmia may occur frequently when prophylaxis is omitted. Complete prevention by local measures applied to the eyes is doubtful. Ophthalmia is cured so readily by an injection of a proper dose of penicillin that reliance should be placed on this treatment rather than on prophylaxis alone. Not a single case of blindness or serious eye lesion resulted from any of the 49 cases of gonococcal ophthalmia.

Conclusions

1. In 1955 permission to use various methods of prophylaxis against ophthalmia neonatorum was granted by the Board of Health in New York City. At the end of 1956 the mandatory requirement of prophylaxis was abolished. The methods used and the results obtained during the three years 1956-1958 by the 96 hospitals in the city where 472,580 infants were born are presented.

2. During this period there occurred 49 cases of gonococcal ophthalmia, 22 among approximately 86,000 infants who received no prophylaxis, one among 14,000 infants in whose eyes salt solution was instilled, 17 among some 259,000 infants who had silver nitrate solution instilled in their eyes, nine among 80,000 infants who were treated prophylactically with antibiotic ointments or solutions, and none in 33,000 who received an intramuscular injection of 50,000 units of penicillin.

3. Only one case of gonococcal ophthalmia occurred among 291,000 private patients. The others were in ward patients. The incidence in Negro patients was about 20 times as high as in white patients; and among white patients seven times as many cases occurred in infants of Puerto Rican origin.

4. Host and environmental factors were found to be as important as the type of prophylaxis used. In areas with

poor health records and high incidence of venereal disease local prophylactic measures often failed. In districts with better health records, cases did not occur whether prophylaxis was used or not, and if used, without respect to the method of prophylaxis.

5. Silver nitrate solution as a prophylactic measure has never been properly evaluated. In the present study, the results of different prophylactic treatments in one hospital show that the incidence of gonococcal ophthalmia was significantly lower when silver nitrate was used than when no prophylaxis was used among newborn infants where comparable risk of infection could be reasonably assumed. Two cases of gonococcal ophthalmia occurred among 7,219 infants treated with silver nitrate solution, a rate of 0.28 per 1,000, and eight cases among 1,996 infants who had no prophylaxis, a rate of 4.00 per 1,000.

6. At the same institution, bacitracin ointment was found to have no value as a prophylactic. Seven cases of gonococcal ophthalmia occurred when it was used in 1,935 infants, a rate of 3.63 per 1,000 live births.

7. While only two cases of gonococcal ophthalmia occurred among 78,376 infants when other antibiotic ointments and solutions were used, and no cases among 33,199 infants treated at birth with an injection of 50,000 units of penicillin, no valid conclusions can be made regarding the efficacy of these preparations since the risk of infection among these infants was not determined.

8. Host and environmental factors should be considered in determining whether prophylaxis should be used. Because prophylaxis is not always effective, reliance should be placed on observation of the baby's eyes in the postpartum period. No case of blindness or of serious eye injury occurred in the 49 cases of gonococcal ophthalmia in New York City. An injection of a proper

dose of penicillin cured the disease promptly.

9. Mandatory prophylaxis does not appear to be necessary in New York City. Prophylaxis should be used in those areas of the city where the risk of infection is high, and omitted where it is low.

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Continuing Education: Radiation Hazards

The Division of Radiological Health, Public Health Service, is sponsoring two newly developed courses for medical personnel having responsibilities in this field. Both will be held at the St. Louis University School of Medicine. The first is "Medical Aspects of Radiological Health," July 10-August 4, which is designed primarily for federal, state, and local health personnel and for university staffs who are incorporating radiological health training in their curriculums. "Epidemiology of Radiation Injury," August 7-18, is for those who are establishing or designing radiation epidemiology programs, and for university research or teaching staffs.

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