EPIDEMIOLOGIC STUDY OF OPHTHALMIA NEONATORUM AND IMPACT OF PROPHYLAXIS ON ITS INCIDENCE

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Abstract- Prevention of ophthalmia neonatorum (ON) in the delivery room has been recommended by the Iranian Ministry of Health and Medical Education only if the mother is affected by STDs. This study aimed at finding out whether the neonatal wards should do prophylaxis as recommended or it is necessary to revise the previously-related protocols. In a randomized clinical trial, 130 full-term neonates born vaginally were selected on simple method in a period of three months and were divided randomly into control and case groups in such a way to be compatible regarding weight, gestational age, and sex. After obtaining parents’ permission, 0.5% erythromycin ointment was used for ON prophylaxis. All the newborns were then examined regarding the presence of conjunctivitis during the third and the tenth day of life. The results showed that totally 8 newborns were affected with conjunctivitis, 7 of whom (87.5%) belonged to the control group and 1 to the case group (12.5%). However, this difference was not significant. This finding might be due to the inadequate frequency of affected subjects in comparison to the whole subjects under study. Considering other studies showing significant effect of drugs used in ON prophylaxis (silver nitrate, tetracycline, erythromycin, povidone-iodine) and based on the results of this study, it is highly recommended that neonatal wards of hospitals in our country carry out prophylaxis of ON in all subjects.

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Key words: Prophylaxis, newborn, conjunctivitis, incidence

INTRODUCTION

Ophthalmia neonatorum (ON) is the most common ocular disease of the newborns which may be caused by bacterial (chlamydial, gonococcal, staphylococcal), viral (herpes simplex), or chemical (silver nitrate) agents.

Based on etiology, symptoms and prognosis of ON differs (1-3). Gonococcal ophthalmia begins earlier in time and is more severe than the chlamydial infection. If gonococcal infection is not treated, it leads to fulminant conjunctivitis which is associated with peripheral ulceration, corneal haziness, formation of ring abscess, and eye perforation. The chlamydial infection which is the most common conjunctivitis of the newborn is usually mild and rarely leads to conjunctival and superficial corneal scarring (2-3). The infection caused by Staphylococcus aureus and other microorganisms is indicative of infection which has been caused during the neonatal period in the society. Pseudomonas conjunctivitis is often observed in the premature newborns and is accompanied with systemic complications.

Conjunctivitis caused by Neisseria gonorrhoea and chlamydia, group B streptococci (GBS), and
Herpes simplex is usually acquired while newborns pass through vagina and indicates the prevalence of sexually transmitted disease (STDs) in society. In other words, the possibility of ON depends on the quality of cares during pregnancy, and the preventive measures which causes conjunctivitis during delivery and after birth (2-4).

We conduct this study to answer the following question: considering the pandemic state of AIDS and because it is usually accompanied with other STDs that could threaten newborn's health, is it actually necessary to do ON prophylaxis routinely or as it recommended by the Iranian Ministry of Health and Medical Education only if the mother is affected by STDs?

**MATERIALS AND METHODS**

To determine the incidence of ON and the effect of prophylaxis on it, full term neonates born through the birth canal in 22 Bahman Hospital affiliated to Gonabad University of Medical Sciences were selected in a randomized clinical trial during a three-month period.

The gestational age of these newborns ranged from 37 to 40 weeks, most being in 37-week group with a frequency of 65.4 percent. All of them were born through the birth canal (those who were born through Cesarian section were removed from the study). Then, the clinical examinations were done and the gestational age, weight and sex of the newborns were determined.

The newborns were randomly divided into two groups of control and case ones. In the case group the conjunctival sac of both eyes were filled with 0.5% erythromycin ointment which is one of the commonly used drugs in prophylaxis of ON. In control group no prophylaxis was done which is based on the Ministry of Health and Medical Education protocols in which conducting prophylaxis has been announced unnecessary, and it is not practiced at the present time.

Ethical committee approved design of this study and we obtained informed consent from parents of all participants.

The mothers were asked to return to the clinic after the third and tenth days of their delivery to control their newborns regarding conjunctivitis. Thus, all the neonates were examined on the third and tenth days after birth and in case of observing the signs of inflammation or conjunctival discharge, an observation form was filled out and then sent to the laboratory for culture and smear.

To collect data, a questionnaire containing the characteristics of each mother and her neonate was used. The collected data were analyzed through SPSS software. The Fisher test was employed to compare the variables, and $P < 0.05$ considered significant.

**RESULTS**

A total of 130 newborns, 54.6% male and 45.4% female were included in the study. The newborns in the two groups were compatible regarding age, weight, and sex ($P$: 0.8, 0.59 and 0.16, respectively) (Table 1).

Totally, 8 newborns were affected with conjunctivitis, 7 of whom (87.5%) belonged to the control group and 1 to the case group (12.5%) for whom erythromycin as a prophylactic drug was applied. In other words, of all the cases studied, 10.8% of the control group and 1.5% of the case group were affected with conjunctivitis (Table 2). Using Fisher test, the difference between the two groups was not significant despite a difference as much as seven times in incidence, a condition which could be due to the inadequate number of affected samples in comparison to the whole population under study.

**Table 1. Baseline characteristics of newborns**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Case</th>
<th>Control</th>
<th>df</th>
<th>95% conf.</th>
<th>$P$ value</th>
<th>Used test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth weight</td>
<td>3158.62</td>
<td>3168.62</td>
<td>128</td>
<td>-154+134</td>
<td>0.89</td>
<td>$t = -.137$</td>
</tr>
<tr>
<td>M/F ratio</td>
<td>1.9</td>
<td>1.3</td>
<td>1</td>
<td>-</td>
<td>0.59</td>
<td>$X^2 = .27$</td>
</tr>
<tr>
<td>Gestational age</td>
<td>37.51</td>
<td>37.77</td>
<td>128</td>
<td>-59+.10</td>
<td>0.16</td>
<td>$T = -1.04$</td>
</tr>
</tbody>
</table>

Abbreviation: M, male; F, female
Table 2. Conjunctivitis incidence among those who have received prophylaxis or not

<table>
<thead>
<tr>
<th></th>
<th>Conjunctivitis Observed</th>
<th>Not observed</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Count</td>
<td>Percent</td>
<td>Total</td>
</tr>
<tr>
<td>Case</td>
<td>1</td>
<td>1.5%</td>
<td>100.0%</td>
</tr>
<tr>
<td></td>
<td>64</td>
<td>98.5%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Prophylaxis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percent of prophylaxis</td>
<td>12.5%</td>
<td></td>
<td>50.0%</td>
</tr>
<tr>
<td></td>
<td>52.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>7</td>
<td>10.8%</td>
<td>100.0%</td>
</tr>
<tr>
<td></td>
<td>58</td>
<td>89.2%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Percent of Conjunctivitis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>87.5%</td>
<td></td>
<td>50.0%</td>
</tr>
<tr>
<td></td>
<td>47.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>8</td>
<td>100.0%</td>
<td>130</td>
</tr>
<tr>
<td></td>
<td>122</td>
<td>100.0%</td>
<td></td>
</tr>
<tr>
<td>Percent</td>
<td>100.0%</td>
<td></td>
<td>100.0%</td>
</tr>
</tbody>
</table>

**DISCUSSION**

Blindness due to ON has been an important problem of developing countries and at present conjunctivitis is one of the important diseases that cause visual loss in the first month of life (5).

During the 19th century, ON was the leading cause of blindness in European children but ON and blindness due to it have significantly decreased since 1881 after Cred suggested prophylactic cleaning of the eyelids at birth followed by insufflation of silver nitrate 1% (1-3, 5).

Different studies have shown that conjunctivitis is relatively high in societies where ON prophylaxis is not done, although determining the exact incidence of this disease is difficult and depends on various factors (6). The studies on African children showed the prevalence of gonococcal infections in mothers as 3-22 percent and 30-50 percent of exposed newborns were affected. In the studies conducted in the UAE, ON is a prevailing problem in neonatal wards but it is seldom because of sexual diseases. In a study in that country which included 81 neonates affected with ON, it was recognized that 81.5% of them had bacterial or fungal infections and the gonococcal type included 5% of other causes (6).

In the United States, the incidence of ON due to chlamydial has been reported as 8 per 1000 live birth and due to gonococcal infection 3 per 1000 live births (2).

Various studies have proven the effect of prophylaxis on decreasing the ON. In a study carried out in Nairobi, the effect of silver nitrate 1% and tetracycline ointment in a controlled clinical trial which included 2732 newborns was investigated. The transfer rate of gonococcal infection using silver nitrate and tetracycline showed a decrease of 83% and 93%, respectively. The transfer rate of chlamydial infection using silver nitrate 1% and tetracycline was 68% and 77%, respectively. Accordingly, the incidence of gonococcal ophthalmia after applying silver and tetracycline were 0.4% and 0.1%, respectively (7).

In another work, the use of povidone–iodine solution 2.5 % had significant effect on prophylaxis of ON. The researchers mentioned the incidence of gonococcal ophthalmia applying silver nitrate, erythromycin and povidone–iodine 0.4%, 1% and 8%, respectively. Also, in that study the incidence of non–gonococcal ophthalmia using silver nitrate, erythromycin, and povidone–iodine has been reported as 17.1%, 14.2% and 12.3%, respectively (8). The use of povidone–iodine is not only effective in preventing gonococcal and chlamydial infections but also in killing the Herpes virus and HIV (8-9-10). But this drug is not available in our hospitals in Iran.

In our study the incidence of ON was 10.8% which was reduced to 1.5% using erythromycin. In conclusion, four levels of intervention in preventing blindness and damages due to ON are recommended: 1) prevention of STDs whose diminution of its incidence leads to a decrease in ON (3-4); 2) ON can be prevented through screening pregnant women regarding genital infection (11-12). Even in some studies the treatment of infected mothers has been more effective than prophylaxis (13); 3) preventing the ocular infection at birth. This is a simple and
cost-effective way and includes cleaning, eyelids with a dry swab immediately after birth and then applying one of the available antimicrobial agents for ON prophylaxis. It has been recognized that tetracycline ointment 1%, povidone iodine solution 2.5% and erythromycin 0.5% ointment are more effective than silver nitrate. Gentamycin and norfloxacin drops have also been found to be effective in one study (14); and 4) The early diagnosis and adequate treatment of ON especially in gonococcal type will prevent corneal ulceration and blindness (1-3).

In order to eliminate blindness and other complications due to ON, it is necessary to have a kind of cooperation and coordination among gynecologists, pediatricians, ophthalmologists and all the staff of the first health cares. As it was pointed out in this study, the incidence of ON in the neonates of the case group who didn’t receive prophylaxis was significantly different in comparison to that of the control group.

In respect to all of the current and valid references which recommend prophylaxis as an essential and reasonable measure after birth, revising the suggested schedules of the Ministry of Health and Medical Education that recommend to apply ON prophylaxis if the mother is affected by STDs and requiring the neonatal wards to use one of the prophylactic agents especially povidone-iodine drop or erythromycin ointment whose cost-effectiveness have been proved in many studies seem necessary.

Conflict of interests
We have no competing interests.

REFERENCES