

Evaluation of preventive effects of colostrum against neonatal conjunctivitis: A randomized clinical trial

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ABSTRACT

Background: Neonatal conjunctivitis leads to several ocular consequences in the affected neonates such as blindness. Currently available therapeutic options include NaNO₃, Gentamicin, Neomycin and so on, in which each of them has their own limitations. Regarding the immunologic content of colostrum and its safety and easy accessibility, we aimed to evaluate its preventive effects against neonatal conjunctivitis. **Materials and Methods:** In this clinical trial, conducted from November 2011 to July 2012, 300 preterm neonates, with culture negative eye swab, were enrolled and randomly assigned into three groups. The intervention group received two drops of colostrum. Control group received no treatment and other neonates were treated with topical Erythromycin ointment (0.5%). All neonates were followed for occurrence of clinical conjunctivitis for 28 days. Data analysis were performed by Chi-square test. **Results:** Our data demonstrate the beneficial preventive effects of Colostrum against neonatal conjunctivitis ($P = 0.036$). **Conclusion:** Colostrum is suggested as an alternative prophylactic option for antibiotics against neonatal conjunctivitis. As colostrum is easily accessible without cost, potential hazards and side effects, public education about its topical favorable effects is worthwhile.

Key words: Antibiotic prophylaxis, colostrum, neonatal conjunctivitis, ophthalmia neonatorum

INTRODUCTION

Neonatal conjunctivitis produces various complications for the neonate in the infancy period or further life stages.^[1] Some of the common complications of the neonatal conjunctivitis include pseudofollicular formation in tarsal conjunctiva, nasolacrimal obstruction and blindness. The

main pathologic organism responsible for the incidence of neonatal conjunctivitis is *staphylococcus aureus*.^[2,3]

Nowadays, different chemical prophylaxis is used worldwide for prevention of neonatal conjunctivitis like AgNO₃, Erythromycin, Gentamicin, Neomycin, Chloramphenicol, Tetracycline and Povidone–Iodine.^[4-7] Each of them has their own limitations and side effects. AgNO₃ has no coverage on the Chlamydia Trachomatis, thyroid disorders due to the application of Povidone–Iodine and so on.^[8] The great failure rate of these prophylactic strategies draw attentions toward novel methods with enhanced safety. In studies performed by Ighanesebhor, it has been demonstrated that sensitivity of *Staphylococcus aureus* and *Escherichia coli* to Gentamicin were 100% and 42%, respectively.^[9] The sensitivity rate of *E. coli* to Colostrum and mature milk were 57% and 28%, respectively.^[9] *Staphylococcus aureus* organisms were sensitive to Colostrum and mature milk in about 0.50% and 0%, respectively.^[9] Growth inhibition zone for *S. aureus* and *E. coli* were between 3 and 5 mm, while marginal or none prevention for mature milk and Colostrum were seen with

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E. coli and *S. aureus*, respectively.^[9] Mean preventive period for Colostrum and mature milk were 6 and 3 h, respectively.^[9] Mature milk has been shown to exert 28% inhibitor effect on *E. coli* organisms for about 3 h *in vitro* and no effect on *S. aureus* organisms. Using Colostrum, this effect was seen to be $\geq 50\%$ against *S. aureus* and *E. coli* organisms for about 6 h, which is much more than mature milk.^[10]

These data favors the use of Colostrum as a cheap, safe and effective agent in the prevention of blindness induced by *Neonatorum Ophthalmia*. Thus the aim of this study was to investigate the possible protective role of the Colostrum droplets in neonates rather than conventional currently available agents used for the routine pediatric care.

MATERIALS AND METHODS

This randomized clinical trial was approved by the Ethics committee of Isfahan University of Medical Sciences, Isfahan, Iran. Written informed consent was obtained from parents. It was conducted from November 2011 to July 2012.

Prior to the study, an analysis was performed to estimate the necessary patient number in each group required to detect a between-group difference of one SD or less, with a 90% power and an error of less than 0.05. Based on the biological variability described in previous studies, a minimum of 80 patients was calculated for each group.^[9]

Overall, 300 preterm neonates, with culture negative eye swab, were enrolled and then by using the table of random numbers, they were randomly assigned into three groups. We selected preterm neonates only because the maternal milk of the premature neonates contain more antibodies and immunologic components; obtaining more valuable data seems possible using their milk. The intervention group received two drops of colostrum in each eye. For applying the Colostrum, we disinfected the nipple first and then we cut the head of one 10 cc sterile syringe with a sterile bistoury and putted the open head around the nipple and pulled back the piston; negative pressure make the colostrum come to syringe. Control group received no treatment and other neonates were treated with topical Erythromycin ointment (0.5%). All neonates were followed for occurrence of clinical conjunctivitis for 28 days. Using swab, ocular culture from each participant was examined and neonates with positive eye cultures were excluded from the study. All treatments were used once and immediately after birth. Parents of all of the neonates signed the assigned contest form. Premature neonates were followed up for a period of 28 days after birth for the incidence of neonatal conjunctivitis, weekly or at the time of the occurrence of symptoms of neonatal conjunctivitis. The study was double-masked, the parents and the person who followed up the patients were not aware about the treatment used. Data were gathered in pre-prepared forms and were analyzed using Chi-square test by SPSS version 17.0.

RESULTS

Data of 268 neonates were complete and were included to the analysis. As presented in Table 1, the frequency of conjunctivitis was higher in the control group, followed by the group receiving topical colostrum and the group receiving topical antibiotic ($P = 0.03$).

The results of eye swab culture of all patients reported *Staphylococcus aureus*.

DISCUSSION

Regarding the main goal of this investigation, our results demonstrate the effective role of colostrum in the prevention of neonatal conjunctivitis. This is in accordance with the results of the Ibhaesbler *et al.*, who demonstrated the positive effects of colostrum on the organisms involved in the pathogenesis of neonatal conjunctivitis.^[9] Despite of the well-recognized role of the breast feeding on the prevention of some infectious diseases as Giardiasis and acute Otitis media in neonates, there are limited data regarding the focal effectiveness of the maternal milk and especially Colostrum.^[11,12] Local application of maternal milk on the human umbilical vein has been shown to be associated with accelerated umbilical separation and decreased focal infection.^[13]

The immunologic efficacy of maternal milk has been investigated by several authors. It has been demonstrated that maternal milk especially Colostrum contain leukocytes and various kinds of immunoglobulins.^[14] Thus the preventive effect of the Colostrum in the case of neonatal conjunctivitis might be associated with the immunological properties of the Colostrum. Although the effect of Colostrum in our study was not similar to the antibiotic effect, Colostrum can be suggested as a second choice for antibiotics application. The absence of side effects in the case of Colostrum, in contrast with antibiotics, is also noteworthy.

Due to the limited available data in this regard, further confirmatory investigations seems necessary. Since the maternal milk of the premature neonates contain more antibodies and immunologic components, obtaining more valuable data seems possible using their milk. Finally, maternal education and exclusive breast feeding are the most fundamental measures decreasing the incidence of various kinds of infections as neonatal conjunctivitis.

Table 1: Frequency of conjunctivitis in the three groups of neonates

	Conjunctivitis		Total
	No	Yes	
Colostrum	68	21	89
Topical antibiotic	69	13	82
Control	65	32	97
Total	202	66	268

$P=0.036$

CONCLUSION

Colostrum is suggested as an alternative prophylactic option for antibiotics against neonatal conjunctivitis. Colostrum is easily accessible without potential hazards and side effects. Public education about such favorable effects of topical colostrum would be worthwhile.

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