

Comparing the Effectiveness of Chlorhexidine Versus Ethanol against Preventing Cord Infections in Neonates Born in a Tertiary Care Hospital

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Abstract

Objective: To compare the frequency of omphalitis with 4% chlorhexidine versus ethanol for cord care in neonates born in a tertiary care hospital

Methods: It was randomized control trial and place of study was Department of Obstetrics & Gynecology, Services Hospital, Lahore. Study period was 6 months i.e. from (12-09-2017) to (12-03-2018). Data was collected from a total of 80 cases. Then females were randomly allocated in two groups. In group A, females were advised to clean the umbilical cord stump of neonate with 4% chlorhexidine. In group B, females were advised to clean umbilical cord with ethanol. Omphalitis was noted. Data was entered and analysed by using SPSS version 20.

Results: The c-section delivery was done in 45 number of patients (56.25%), SVD was done in 29 number of patients (36.25%) and instrumental delivery done in 6 number of patients (7.50%). Omphalitis was noted in 27 number of patients (33.75%), out of which 7 were from Chlorhexidine group and 20 were from ethanol group (p-value=0.002)

Conclusion: According to study of Özdemir H et al risk of omphalitis was found significantly reduced with use of 4% chlorhexidine as compared to use of ethanol for cord care.

Keywords: omphalitis, neonates, ethanol, chlorhexidine, cord care

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Introduction

Omphalitis or infection of umbilical cord of a neonate can have serious sequelae. It is risk factor for neonatal sepsis and mortality.

Contamination of cord during delivery or in post-partum period can lead to omphalitis. It is characterized by oozing of puss from cord and redness/swelling around base of cord. Pathogens can enter in general circulation through newly cut patent blood vessels and can cause neonatal sepsis.¹ Various researchers have studied the intervention which can reduce the incidence of ompha-

litis and sepsis. These include clean delivery kits, training in hygienic birth practices, frequent hand washing of care givers, daily cord cleansing by anti-septic till cord separates.^{2,3}

Nearly 3.3 million neonatal deaths per year occur around the world. Among these 98 % of neonatal deaths occur in developing countries, more than half of these are associated to home birth and one third of these are due to infection.^{4,5} In 2013, nearly 2.6 million neonates died before one month of age, down from 4.5 million in 1990.⁶ Infection related neonatal mortality in home births in developing countries is a significant public health concern.⁷ About 2-15% of neonate with omphalitis develops systemic sepsis and die.⁸

Various home remedies have been used to facilitate safe and early cord separation. Traditionally, hot oil, petroleum jelly, gentian violet or even cow dung have been applied to the cord. Topically antimicrobials for cord care include ethanol, silver sulfadiazine povidone iodine and chlorhexidine.

Chlorhexidine has been used in infection control for many years. There is no evidence of any bacterial resis-

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tence so far. Its use has shown to reduce the bacterial colony counts. Therefore, use of chlorhexidine for cord cleansing seems to be promising.

This study is conducted to compare the frequency of omphalitis with use of 4% chlorhexidine compared to ethanol for neonates born in a tertiary care hospital. Literature has reported that 4% chlorhexidine is an effective agent to prevent infection of umbilical cord and associated complications.⁸ 4% chlorhexidine is relatively new in Pakistan and this study is conducted to study its effectiveness for umbilical cord care in new born babies. Our study will help us to improve local practice to implement the application of 4% chlorhexidine for cord cleansing.

Material & Methods

Randomized Controlled Trial. Department of Obstetrics & Gynecology, Services Hospital, Lahore. The Study period was Six months i.e. from (12-09-2017) to (12-03-2018). A total of 80 cases were included in the study. None of patient was lost to follow-up. 40 cases were recruited in each groups, calculated with 80% power of test and 5% level of significance. Expected percentage of omphalitis was 25% with chlorhexidine and 57.7% with ethanol used for cord care.⁹ Non probability consecutive sampling.

Females with 18-40 years of age, delivered at gestational age ≥ 37 weeks (as per LMP) were included. Females with gynecological pelvic infections at the time of recruitment in the study, Urinary tract infection or with hepatitis A, B or C were excluded.

80 cases who met the inclusion criteria were included in this study. Information was collected on a predesigned proforma. Informed consent was acquired. Women were randomly divided into two groups by using lottery method. In group A, females were advised to clean umbilical cord of neonate once a day with 4% chlorhexidine. In group B, females were advised to clean umbilical cord twice daily with ethanol. Hospital staff educated the mothers and helped for proper application of antiseptic to the cord. Then neonates were followed-up daily till discharge. All the women included in the study were followed by telephone. They visited OPD on the 7th postnatal day. None of the patient was lost to follow up. Umbilical cord of neonate were assessed and noted on predesigned proforma for the presence of signs of infection i.e. necrosis, pus discharge, swelling and redness of umbilical cord stump. Neonate with clinical omphalitis were referred to neonatology Unit for puss culture and further management.

Data was entered and analyzed by SPSS version 20.

Quantitative data such as age of women and gestational age at the time of delivery presented as mean and standard deviation. Qualitative data like mode of delivery and omphalitis was calculated as frequency and percentage. Both groups were compared by using chi-square test. p-value of ≤ 0.05 was taken as significant.

Results

A total of 80 cases were studied. In Chlorhexidine group patients the mean age was 29.28 ± 5.643 years whereas in ethanol group patients it was 30.30 ± 6.903 years. The mean gestational age at delivery was 39.13 ± 1.83 weeks in the Chlorhexidine group whereas in ethanol group it was 38.98 ± 1.51 weeks. C-section was done in 45 patients in which 20 were from Chlorhexidine group and 25 were from ethanol group, SVD was done in 29 cases in which 15 cases were from chlorhexidine group and 14 were from ethanol group. While the instrumental delivery was done in total of 6 patients among which 5 were from Chlorhexidine group and 1 was from ethanol group. (Table-1)

Omphalitis was noted in 27 out of 80 patients (33.75%), Table-2

Table 1: Comparison of Predictive Values (Bishop Score vs. Cervical Length)

	Study Groups	
	Chlorhexidine	Ethanol
n	40	40
Age (years)	29.28 \pm 5.64	30.30 \pm 6.90
Gestational age (weeks)	39.13 \pm 1.83	38.98 \pm 1.51
Mode of delivery		
C-section (No. of patients)	20	25
SVD (No. of patients)	15	14
Instrumental delivery (No. of patients)	5	1

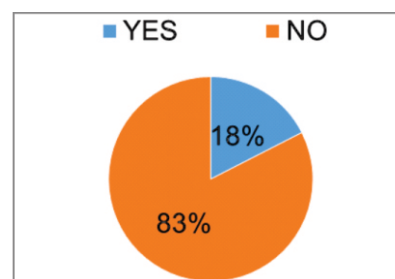


Figure-1: Development of Omphalitis in Chlorhexidine group

In this study the Omphalitis was observed in 27 babies, 7 from these were from Chlorhexidine group and 20 were from ethanol group. Omphalitis did not develop in 53 cases. 33 out of these 53 were from chlorhexidine group and 20 were from ethanol group. Regarding the omphalitis status of the patients, difference between the study groups was statistically significant i.e. p-value

Table 2: Comparison of omphalitis in both trial groups

	Trial Group		Total
	Chlorhexidine	Ethanol	
Omphalitis	Yes	7	27
	No	33	53
Total	40	40	80

Chi value=9.448, p-value=0.002*

= 0.002. (Table-2)

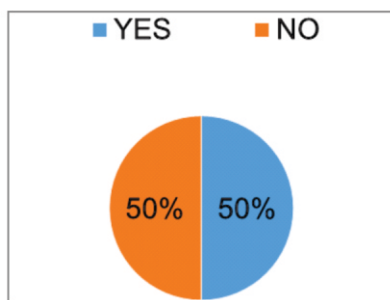


Figure 2: Development of Omphalitis in Ethanol Group

Discussion

Omphalitis is one of the initial presentation for the development of serious neonatal infections including sepsis and tetanus. Umbilical cord treatment has decreased the incidence of omphalitis and neonatal sepsis in developed countries. Whereas, in developing countries omphalitis is still a significant cause of infant mortality.^{10,11}

Omphalitis is a medical term for inflammation of the umbilical cord stump during the neonatal life which is typically caused due to bacterial infection.¹²⁻¹⁴ There doesn't seem to be any form of racial or ethnic profiling.¹⁴ Omphalitis, like all bacterial infections, is more prevalent in babies with a compromised or impaired immune system, as well as those who are hospitalized and undergo intrusive procedures. As a result, babies who are premature with other infections like sepsis or pneumonia, or have immune defects are more susceptible.¹⁴

Omphalitis was observed in 27 of the patients (33.75%) in our sample, with 7 (17.5%) from the Chlorhexidine group and 20 (50%) from the ethanol group. The sample groups with omphalitis had a statistically important difference, with a p-value of 0.002. The findings of our research are close to those of a Japanese study performed by Oishi et al. They observed that 25 percent of neonates developed omphalitis when given 4 percent chlorhexidine, while 57.7% developed omphalitis when given ethanol ($p \leq .05$). They concluded that disinfection on a regular basis with 80 per-cent ethanol containing chlorhexidine was more successful than disinfection

with 80 percent ethanol alone in preventing colony formation of *Staph. Aureus* on the neonatal umbilicus.⁹

Another method of cord care is dry cord treatment. It is practiced in low resource countries. In India a research performed by Gathwala et al. chlorhexidine cord cleansing was found to have less complications than dry cord treatment. A total of 140 people were enrolled and examined. In this study statistical variation was observed between the groups regarding time of cord separation and frequency of sepsis, but there was no statistical difference in terms of umbilical infection, suspected sepsis, or meningitis. The researchers concluded that application of chlorhexidine to the umbilical cord in the neonatal units avoids sepsis.¹⁵ Trials were conducted by Gathwala et al., and Kapellen et al. They concluded that the chlorhexidine for cleansing of cord after birth was associated with less incidence of developing the omphalitis.^{15,16} Another trial done by Sharma et al., showed that using chlorhexidine for the treatment of umbilical cords decreases cord isolation time and neonatal death in ne-onatal intensive care units. They concluded that application of chlorhexidine helps to minimize neonatal mortality. It was observed that in terms of time duration taken for separation of cord (8.92 2.77 days versus 10.31 3.23 days; $t = 2.20$; $p = 0.02$) and neonatal mortality ($p = 0.042$), there was a substantial differential between classes. As a result, using chlorhexidine for umbilical cord treatment lowers cord isolation time and neonatal death in the NICU.¹⁷

A research conducted on 9,741 babies delivered at home in Pakistan studied the effects of chlorhexidine therapy versus hand washing alone. Each baby was followed for 14 days. The results showed little influence of hand washing on the occurrence of umbilical cord infection or neonatal mortality, but a major decrease in both umbilical cord infection (RR = 0.58, 95 % CI 0.41-0.82) and neonatal mortality (RR = 0.58, 95 % CI 0.41-0.82) was noted in the chlorhexidine arm. Thus, the use of 4 percent chlorhexidine in rural Pakistan, reduced the incidence of both omphalitis and neonatal mortality. The study recommended for the addition of chlorhexidine in birth kits. It may prove to be an important addition for decreasing neonatal mortality.¹⁸ In a study conducted in Bangladesh the investigators compared dry cord treatment, one application of 4 percent chlorhexidine soon after birth, and several chlorhexidine (up to 7) applications. It was a three arm cluster randomized analysis based on home births.¹⁹ Chlorhexidine Working Group in Pakistan in collaboration with government services performed an efficacy trial. In one group chlorhexidine was applied on umbilical cord of new born babies from home deliveries on the day of birth and for upto next two weeks, while control group was counselled to practice dry cord care.²⁰

World Health Organization has been encouraging the use of dry umbilical cord care on a global scale since 1998. The American Academy of Pediatrics also argued that no antiseptic procedure is preferable to any other, and the German Association for Neonatology and Pediatric Intensive Care also advises that the umbilical cord be kept safe and dry.²⁰

On the other hand, in home and those hospital births where hygienic settings are difficult to achieve, there is an elevated risk of severe neonatal contamination triggered by exposure of the umbilical cord to infections.²¹ In 2014 WHO updated guidelines for umbilical cord care. It recommends the use of chlorhexidine for first week of life in settings with high neonatal mortality.

Our study also shows that chlorhexidine treatment is a low cost, easy to apply intervention which significantly reduces the umbilical cord infection.

Conclusion

It was concluded that use of 4% chlorhexidine for umbilical cord care showed significantly reduced omphalitis than to ethanol group for neonates born in a tertiary care hospital.

Conflict of Interest

None

References

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Authors Contribution

SR: Conceptualization of Project

HB: Data Collection

TR: Literature Search

GA: Statistical Analysis

AS: Drafting, Revision

BA: Writing of Manuscript