

Chlorhexidine for the Prevention of Omphalitis in neonates with a single dose

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ABSTRACT

Background: Worldwide, 44% (2,761 million) of the 6 million children who died before the age of five in 2013 did so during the newborn period. Globally, the first week of life is when 75% of newborn fatalities occur. Low-middle income nations account for 99% of newborn death worldwide. A great proportion of these neonatal deaths can be prevented if effective health measures are undertaken during birth giving prime importance to hygiene.

Aim: To evaluate the effectiveness of a single application of chlorhexidine in the prevention of Omphalitis in neonates.

Methodology: This randomised control experiment was carried out between October 2021 and April 2022, in the paediatrics unit of the Hayatabad Medical Complex in Peshawar. In this study, a total sample size of 64 with 32 in each group was observed. Newborn infants were randomly assigned to two types of cord care regimes, Group-A and Group-B. In Group-A newborns, the umbilical cord was cleansed with a single application of 4% chlorhexidine solution, and newborns in Group-B were instructed to leave the cord dry. The outcome of the study was the presence or absence of Omphalitis for which follow-up was done by the researcher on days 7th, 14th, 21st, and 28th of life in the hospital or through a home visit, whichever was acceptable to parents. The outcome measurement was recorded through proforma.

Results: In this study mean age in Group A was 7 ± 2.77 days. Whereas the mean age in Group B was 7 ± 3.12 days. In group-A Fifty-six percent of neonates were male and 44% of neonates were female. Whereas in Group B 53% of neonates were male and 47% of neonates were female. 94% of patients responded favourably to additional chlorhexidine solution, whereas 6% did not. whereas Group B dry cord was successful in preventing Neonatal Omphalitis in 78% of cases and failed in 22% of individuals.

Practical implication: With the use of chlorhexidine in newborn prevent neonates from sepsis and reduce mortality and morbidity.

Conclusion: Our study concludes that a single application of chlorhexidine is more effective than a dry cord in the prevention of Omphalitis in neonates.

Keywords: effectiveness, a single application of chlorhexidine, Omphalitis, neonates.

INTRODUCTION

Worldwide, 44% (2,761 million) of the 6 million children who died before the age of five in 2013 did so during the newborn period¹. Globally, the first week of life is when 75% of newborn fatalities occur^{2,3}. Low-middle income nations account for 99% of newborn death worldwide¹. A great proportion of these neonatal deaths can be prevented if effective health measures are undertaken during birth giving prime importance to hygiene⁴. An umbilical cord infection known as omphalitis affects the cord's surrounding tissue. In the developing nations, omphalitis raises the risk of and death among newborns. Bacteria that can cause newborn sepsis and death easily enter the body through the freshly severed umbilical cord. Via the open blood vessels of the freshly severed cord, bacteria from the mother's vagina and the delivery attendant's hands can readily enter the circulation⁵. To lessen the danger of Omphalitis and mortality, hygienic delivery procedures and postpartum care procedures are strongly encouraged. In the community and primary care context, topical administration of 4% chlorhexidine to the umbilical cord lowers infant mortality and omphalitis in developing nations. A broad-spectrum antiseptic agent, chlorhexidine, is effective against both aerobic and anaerobic pathogens. Although it acknowledges that antiseptics may assist newborns in environments where dangerous agents are customarily used, WHO encourages dry cord care for poor nations. However, the WHO's current advice for dry cord care is based on insufficient data and may not be appropriate in regions with a high incidence of omphalitis^{6,7}.

A Cochrane review by Zupen et al based on 21 trials concluded that the overall evidence was inconclusive for making

specific recommendations for or against the use of any antiseptic. However all the included studies in this review were conducted in hospital settings of high income countries except one which was done in Thailand. However the trials of using antiseptics for umbilical cord care in low and middle income countries have given very promising results in reducing incidence of Omphalitis and neonatal mortality⁸.

According to a study done in Nepal, the WHO recommendations for dry cord care are inadequate in low resource settings where the risk of infections is considerable. Chlorhexidine treatment for topical cord antiseptics is a significant intervention that has the potential to have a significant impact on public health⁹.

Recently, Nepal became the first nation to use chlorhexidine on a large scale for the management of umbilical cords. Chlorhexidine was given the go-ahead by the Nepali government to be used in crucial infant care^{10,11}.

The results of a similar study conducted in Bangladesh concluded that Infants risk of infection and death during the 1st weeks of life can be reduced by as much as 20% by cleansing the newborns umbilical cord with chlorhexidine. Countries in sub Saharan Africa have also moved forward with chlorhexidine for umbilical cord care^{10,11}.

According to a study done in Nepal, Bangladesh, and Pakistan, applying chlorhexidine to a newborn's umbilical cord may result in a 27–56% decrease in omphalitis compared to a control group, depending on the severity of the infection¹². Three studies done in 2013 showed significant reduction in either Omphalitis, neonatal mortality or both with the 4% chlorhexidine¹³.

According to a 2013 study, community-based skin or cord care using chlorhexidine reduces the incidence of omphalitis by 50% and infant death by 12%¹⁴.

The rationale of this study is to evaluate the efficacy of chlorhexidine in preventing omphalitis in newborns. Finding an appropriate preventative measure for this illness, enhancing life

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quality, and lowering the infant death rate are of the highest significance. The results of this study will add an updated and latest analysis to existing body of knowledge and would be useful for practitioners.

MATERIALS AND METHODS

The Paediatrics Department at Hayatabad Medical Complex conducted a 6-month randomised control study from October 2021-April 2022. There were 64 people total, with 32 in each group for this study. Babies were split into two groups, Group A and Group B, based on who would be handling their umbilical cords. The umbilical cords of the infants in Group A were cleansed with a 4% chlorhexidine solution once, whereas those in Group B were instructed to be left alone. The occurrence of Omphalitis served as the study's primary outcome measure, with patients being followed up on in either the hospital or at home on days 7, 14, 21, and 28. Forecasted results based on historical data. SPSS-22 was used to analyse the data. If the data was continuous, like a newborn's age or weight, a mean and standard deviation might be calculated. There was also information supplied in terms of frequency and % for each gender and level of effectiveness. Chi-square analysis was used to compare the results. A p-value of 0.05 is statistically significant. All results were shown in tables and graphs. Age, body mass index, and gender were taken into account as stratification factors. Test for statistical significance using the Chi-square distribution after stratification. The significance level was set at 0.05.

RESULTS

In this study age distribution among two groups was analysed as in Group A 20(62%) neonates were in age range 1-7 days and 12(38%) neonates were in age range 8-15 days. Mean age was 7±2.77days. Where as in Group B 19(59%) neonates were in age range 1-7 days and 13(41%) neonates were in age range 8-15 days. Mean age was 7 ± 3.12 days.

Gender distribution among the two groups was analysed as in Group A 18(56%) neonates were male and 14(44%) neonates were female. Whereas in Group B 17(53%) neonates were male and 15(47%) neonates were female.

Weight distribution among two groups was analysed as in Group A 19(59%) neonates had weight range of 2.5 – 3.0kgs while 13(41%) neonates had a weight range of 3.1- 3.5 Kgs. The mean weight was 3±1.03kgs. Where as in Group B 17(53%) neonates had weight range 2.5 – 3.0kgs while 15(47%) neonates had weight range 3.1- 3.5 Kgs. Mean weight was 3± 1.05kgs.

When comparing the effectiveness of the two groups, Group A (chlorhexidine solution) was successful in 30 (94%) of the patients and ineffective in 2 (6%).Comparatively, Group B (dry cord) had a success rate of 25 (78%) patients and a failure rate of 7 (22%) patients. (Table 1). Stratification of efficacy with respect to age, gender and weight is given in table 2,3 and 4.

Table 1: Efficacy of chlorhexidine

Efficacy	Group A	Group B
Effective	30(94%)	25(78%)
Not effective	2(6%)	7(22%)
Total	32(100%)	32(100%)

Group A: Cleaned with chlorhexidine solution Group B: Dry cord
Chi-Square test was applied in which P value was 0.0721

Table 2: Stratification of efficacy w.r.t age distribution

Age	Efficacy	Group A	Group B	P value
1-7 days	Effective	19	15	0.1339
	Not effective	1	4	
Total		20	19	
8-15 days	Effective	11	10	0.3150
	Not effective	1	3	
Total		12	13	

Group A: Cleaned with chlorhexidine solution Group B: Dry cord

Table 3: Stratification of efficacy w.r.t gender distribution

Gender	Efficacy	Group A	Group B	P value
Male	Effective	17	14	0.2611
	Not effective	1	3	
Total		18	17	
Female	Effective	13	11	0.1642
	Not effective	1	4	
Total		14	15	

Group A: Cleaned with chlorhexidine solution Group B: Dry cord

Table 4: Stratification of efficacy w.r.t weight distribution

Gender	Efficacy	Group A	Group B	P value
2.5 - 3 Kgs	Effective	18	13	0.1136
	Not effective	1	4	
Total		19	17	
3.1 - 3.5 Kgs	Effective	12	12	0.3533
	Not effective	1	3	
Total		13	15	

Group A: Cleaned with chlorhexidine solution Group B: Dry cord

DISCUSSION

A total of 2,761,000,000 newborns are thought to have died in 2013 before reaching their fifth birthday.75% of baby deaths occur in the first week of life.¹ In poor and middle-income countries, the mortality rate for infants was 99 percent. In addition, there may be a correlation between the number of newborn fatalities and the amount of effort put into fostering appropriate birthing circumstances⁴. Umbilical cord and adjacent tissues infection is known as Omphalitis. Premature newborns have little chance against encephalitis. The 7- day average for A and the 2.77-day standard deviation are both results of calculations performed over the same time frame. Seven days was the usual for Subject B. (SD 3.12). With 56% men and 44% girls, the gender ratio in group A was almost ideal. In Group B, more men than women were present (53% vs. 47%). Even after using the chlorhexidine solution, 6% of persons still didn't feel better. For example, in Group B, when babies were given a dry chord, 78% of them did not get Omphalitis, but only 22% of those who did not receive the dry cord did. When administered to the umbilical cord, chlorhexidine has been shown to reduce occurrences of Omphalitis by 27-56%, according to another research (Mullany LC et al¹⁵). That would be the 'sham' group here. With the use of a chlorhexidine solution, Imdad A et al¹⁶ found that 90% of infants were protected against Omphalitis and 82% were protected from a dry cord. Separate research by Goldenberg RL et al¹⁷ also uncovered chlorhexidine skin or cord care links, infant mortality and morbidity¹⁴. According to the research by Sazawal S et al⁸, the total number of infants was 36 911, with equal numbers assigned to the chlorhexidine (n=18015) and dry cord care (n=18 896) groups. Only 17 468 (96%) of the 18 015 babies were tracked down after 28 days; this rose to 18384 (97%) among those who had received dry cord care. When used topically, chlorhexidine helped reduce Omphalitis discomfort. An estimated 24–39% reduction in new infections occurred. Experiments out in Nepal, Pakistan, and Bangladesh yielded similar results¹⁹. Our results are consistent with the hypothesis that there is a higher likelihood of an umbilical hernia. A chlorhexidine wash reduced the risk of cord infection by 32.75% in Nepal and by 1 day in Bangladesh. Go dumb at the stomach.

The Pakistani research found that the rate of Omphalitis of any severity was lower in the chlorhexidine treatment group than in the dry cord care group. Bacteria thrive on umbilical stumps. Inflammation of the stump, also known as otitis Omphalitis, may be quite serious. A systemic illness is fatal for infants less than a year. The health of the arterial walls In the first few days, infections may enter the vascular system if Omphalitis^{20,21,22} is insufficient. The reduction in mortality and improvement in conditions associated with chlorhexidine could be due to sepsis without Omphalitis. Sepsis may occur even in the absence of Omphalitis if the host immune system is unable to eradicate the infection in the umbilical stump. While chlorhexidine administered to the cord stump might help prevent localised infections, patent umbilical capillaries allow bacteria and other organisms to enter the circulation, potentially leading to lifethreatening illnesses including sepsis or even death

23 and 24. Chlorhexidine greatly retards the process of the umbilical cord detaching.

Our research discovered an association between Omphalitis and mortality, but the Bangladesh study found none; this may be due to the fact that we used a more stringent cut-off time for when to separate the umbilical cord. Think about the possible outcomes of delaying cord separation. Compared to the rest of Sub-Saharan Africa, Pakistan and Bangladesh have lower rates of neonatal death. Africa (31 per 1,000). (31 per 1,000). (29). 24 cases for every 1,000 births About 23% of all babies in Nepal are male (23 per 1,000 births)²⁴. The death rate in Africa has seen a dramatic change in recent decades. Both the chlorhexidine and the dry cord care groups had lower than expected rates of surgical-related death (10.5% and 11.7% per 1000 live neonates, respectively). These rates are much higher than the already low rates in Bangladesh (22.5 and 28.3 deaths per 1000 births) and Nepal (14.6 and 19.3 deaths per 1000 births). Overall, the mortality rate decreased from 31.1 per 1000 live births in 2010 to 25.9 in 2015, however it grew from its 2010 low of 24.9. 15 Observing trends over time might shed light on this enigma.

During the course of the study, moms and other family members learned about the need of maintaining clean cords, and it's possible that the fact that this institution adhered to a comprehensive set of cord care practices contributed to a 25% reduction in fatality rates. The findings of the pilot research indicate that dry cord care is well-liked in Pemba. This setting may have provided superior dry cord care than that available in Asian cultures. Preventing infection of the cord stump and reducing neonatal mortality were both unsuccessful in Pemba. Three studies show that using chlorhexidine to clean the umbilical cord lowers the risk of sickness and death in newborns, while the optimum timing and duration of this practise remains unknown. Using chlorhexidine for 1 and 7 days yielded inconclusive outcomes. Bangladesh has to do more research on the Asian and Sub-Saharan African regions before it can really understand them. Cluster randomized experiments with high birth rates (>90%) depended on the population to locate subjects, in contrast to trials²⁴ were out in South Asia. The strength of our findings is enhanced by the variety of our beginning places and methods of design randomized A large-scale (53%), randomized, controlled experiment included both infants delivered at home and those born in hospitals. The controlled studies employed large samples. When comparing the first 24 hours of life in Bangladesh (86%-88%) and Nepal (64%-64%) to those of the two groups, you can see that babies in both were in contact with their carers more often. 93%. Based on our studies, we anticipated a superior chlorhexidine variant. When hiring competent reviewers, bias in the selection process is minimized²⁷. Because of falling death rates, we have less reliable statistics. Similar to the trial that took place in Zambia²⁷, we show that chlorhexidine works, even in resource-poor regions south of the Sahara Desert in Africa. The umbilical cord birth defect rate has not altered.

Our study's independent power is low since the observed death rates were lower than anticipated, which is a limitation. The treatment of chlorhexidine to the umbilical cord in low-resource settings in sub-Saharan Africa, however, had no impact on mortality, as we offer critical first data coupled with a concurrent study in Zambia¹².

CONCLUSION

Our study concludes that single application of chlorhexidine is more effective than dry cord in prevention of Omphalitis in neonates.

Conflict of interest: Nil

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