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CHLORHEXIDINE FOR THE PREVENTION OF OMPHALITIS IN NEONATES WITH A SINGLE DOSE

Dr Allah Nawaz Sultan[1], Dr Faisal Javed[2], Dr Nosheen Iftikhar[3], Dr Shabir Ahmad[4], Dr Iqbal Ahmad Azhar[5], Dr Waheed Ahmad[6*]

[1]Assistant Professor Pediatrics, Pediatric Department, Sharif Medical City Hospital, Lahore. Email: allahnawazsultan@gmail.com
[2]Consultant Pediatrician, Pediatrics Department, Ali Fatima hospital, Lahore, Email: dr.faisal.javed@hotmail.com
[3]Associate Professor of Pediatrics, Pediatrics Department, Sharif Medical City Hospital Lahore Email: dr_4_1@yahoo.com
[4]Associate of Pediatrics, Pediatric Department, Azra Naheed Medical College Lahore & Chaurdhry Muhammad Akram Teaching Hospital Lahore, Email: ashabir76@yahoo.com
[5]Professor of Pediatrics, Azra Naheed Medical College Lahore & Chaurdhry Muhammad Akram Teaching Hospital Lahore, Email: dr_iqbal_ahmad@hotmail.com
[6*]Assistant Professor Pediatrics, Azra Naheed Medical College Lahore & Chaurdhry Muhammad Akram Teaching Hospital Lahore. Email: w_a272002@yahoo.com

***Corresponding author:** Dr Waheed Ahmad
*Email: w_a272002@yahoo.com

Abstract

Objectives: This study aimed to evaluate the effectiveness of a single application of 4% chlorhexidine in preventing omphalitis in neonates compared to standard cord care practices.

Materials and Methods: The study is a randomized control trial which involved 200 neonates with 100 neonates in each of the chlorhexidine group and the control group. Inclusion criteria were live births with an intact umbilical cord at birth while exclusion criteria were neonates with infections and structural anomalies at birth. Therefore, the main focus was on the rate of developing omphalitis during the intended follow-up period.

Results: The frequency of omphalitis in the chlorhexidine group was 8 (8%) compared to 24 (24%) for the control group and the relative risk reduction was 66.67% ($p < 0.01$). Moreover, chlorhexidine was less severe with an average symptom severity score of 2.1 compared to control group's score of 3.5 on average ($p< 0.01$).

Conclusion: This research establishes that use of 4% chlorhexidine reduces the incidence and severity of omphalitis in the neonate hence implying that should be allowed to be used in the neonatal section.

Key Words- Chlorhexidine, Omphalitis, Neonates, Infection Prevention, Randomized Controlled Trial.

INTRODUCTION

Neonatal umbilical cord infection or omphalitis is a major public health concern that causes high disease and mortality in neonates especially in developing country. It is an inflammation and infection

of the stump together with redness and is occasionally complicated with sepsis (1). Neonates are at a high risk of infections because of the relative immaturity of the immune system the umbilical cord stump is an open wound through which bacteria could easily enter. Lack of proper hygiene and traditional cord management like use of other non-sterile products increases the chances of infection and makes omphalitis and important world health issue (2).

Chlorhexidine is also a broad-spectrum antiseptic that has been studied extensively for its usefulness in neonate infection prevention particularly within regions with high neonatal morbidity and mortality coefficients. The WHO recommend the use of 7.1% chlorhexidine gluconate for cord care as it has proved efficient in reducing neonatal infections and increasing survival in newborns (3). Chlorhexidine kills a broad spectrum of bacteria which includes gram-positive, gram-negative bacteria and fungi as well. Used on the umbilical cord stump after delivery, it has become routine practice in most countries, and several research works have affirmed its effectiveness in the prevention of omphalitis (4).

Chlorhexidine neonatal trials have received much attention after the discovery that a single application of the antiseptic can significantly reduce umbilical cord infection rates in newborns. Ishaq et al. conducted a study in Pakistan to find out the role of a single dose chlorhexidine in reducing omphalitis where the results revealed that condition was reducing with help of intervention when compared with traditional cord care practice (1). The study illustrated that the use of one product decreased omphalitis and methods used in cord care were made easier hence making it possible to be applied in developing world.

Randomized control trial carried out by Hussain et al. (2022) in real sense provided strong evidence of differences between clinical neonates receiving chlorhexidine and methylated spirit treatment. Consequently, the efficiency of chlorhexidine was significantly proved much better in preventing both omphalitis and sepsis among the new born with sufficient evidence in favor of the application in neonatal care. This finding is also underlining the use of chlorhexidine as a standard upstream risk reduction strategy especially in the areas with high rates of neonatal sepsis. Moreover, the research revealed that while methylated spirit which is used for umbilical cord care in many cultures was less effective when it comes to preventing infection than chlorhexidine. This emphasizes the need for current antiseptic measures that will possibly provide greater levels of safety to at risk neonates and apparently implies the need for educational assistance.

Besides clinical study, a large and successful public health campaign has been conducted which introduced chlorhexidine as a preventive agent for omphalitis. For example, the NeoCHG trial on five neonatal units successfully proved that chlorhexidine is safe for use in the newborns whether it is applicable with calming or not (8). This trial adds to the evidence that a single dose of chlorhexidine is a feasible and effective approach to decreasing neonatal morbidity from omphalitis.

Even though there is ample supporting data for chlorhexidine use over the antiseptic, its utilization is still inconsistent in different areas because of some reasons including health facility accessibility, cultural beliefs, and knowledge about proper cord care. Kinanu et al (2022) described the difficulty of introducing uniform cord care practices to the rural hospitals in Kenya due to the presence of traditional practices therein (4). The study also established that chlorhexidine was effective but mainly postpartum education helps the mothers as well as the healthcare workers to embrace the product massively.

One of the most important issues which determine the efficacy of chlorhexidine for the omphalitis prevention is the environment within which it is applied. Zhou et al. (2022) and performing a meta-analysis on chlorhexidine cleansing use, the proportion and risk ratio concluded that the effectiveness of the antiseptic could be influenced by the hospital environment and the presence of healthcare-associated infections (10). However, appreciating chlorhexidine in setting with bad hygiene may be reduced by poor infection control practices. Chlorhexidine is a very powerful agent against omphalitis, but it needs to be applied together with other measures to prevent the infection.

Furthermore Besides, Akhtar et al. (2023) on the comparative effectiveness of 4% chlorhexidine with methylated spirit for the prophylaxis of omphalitis and sepsis. In their study carried out in a tertiary care hospital, chlorhexidine was found to be more effective as compared to methylated spirit for the

prevention of omphalitis as well as of neonatal sepsis which further supports the global advice suggesting use of chlorhexidine in neonatal care (3). The authors underlined that chlorhexidine had superior antimicrobial spectrum and longer duration of stay on the surface that demonstrated better efficiency than traditional antiseptics.

In considering the cord care use of chlorhexidine another factor that needs to be taken into consideration is the frequency of its usage. Some protocols call for an application at least once daily during the first week of life, whereas others require only a one-time dose. Ishaq et al. (2020) conducted a study determining the effectiveness of a single dose of 4%, chlorhexidine in preventing umbilical cord infections in which they established that chlorhexidine was more effective in reducing omphalitis prevalence as compared to the traditional usual care (5). This result is consistent with the current trend of using a single solution with chlorhexidine commonly used in resource-limited situations where several interventions are not possible.

In addition, in the study by Singh et al. (2024) Bangladesh and Nepal's national chlorhexidine survey evaluated factors with regard to successful implementation of chlorhexidine for newborn cord care. The cross-sectional review undertaken showed though there was increase in coverage the intervention was still unequally distributed in rural and urban settings where people in rural areas were less likely to access the intervention since there was a lot of room for logistics and people's low awareness (14). Therefore, enrolment of chlorhexidine as a component of neonatal care requires special consideration for users especially in developing world.

Objective: To evaluate the efficacy of a single dose of chlorhexidine in preventing omphalitis in neonates, contributing to improved neonatal health outcomes and enhancing current cord care practices.

MATERIALS AND METHODS:

Study Design: Cross sectional study

Study setting: This research was conducted in the neonatal unit of a tertiary care hospital where neonates could be closely observed and essential teaching directives and care could be provided.

Duration of the study: It was conducted within six months for reasons including neonates' recruitment and follow up, during the crucial neonatal period.

Inclusion Criteria:

The study recruited all the newborns who were admitted in the neonatal unit in the respective study period, irrespective of their gestational age, but every parent signed informed consent.

Exclusion Criteria:

Infants who were allergic to chlorhexidine and those with cord infection at enrolment and the surgical infants were excluded from the study.

Methods:

Neonates in the neonatal unit were randomized to the chlorhexidine group receiving 4% chlorhexidine for one dose or the no chlorhexidine group with routine cord care. The intervention entailed washing and then dipping in chlorhexidine on the umbilical cord stump as soon as possible after birth and assessing for omphalitis for the next one week. Questionnaires were administered for the next five consecutive days through observations of the infant's umbilical cord stump for any clinical sign of inflammation such as redness, swelling, discharge or any sign suggesting a systemic infection.

Assessment was done, and parents were educated on proper cord care, and further assessment was made to check if they had complied with laid down directions. The main dependent variable was the rate of omphalitis confirmed by a pediatrician within two weeks of a positive test result. Qualitative cross-tabulations were analyzed by chi-square tests for categorical data and t-test for continuous

variables at $p < 0.05$. Ethical clearance for the study was sought from the hospital's ethical review committee and all families included in the study signed consent.

RESULTS:

Target recruitment for the study was achieved with 200 neonates and 100 of them were assigned to the chlorhexidine group and the other 100 to the control group. The following design was intended to assess the impact of chlorhexidine rigorously in preventing omphalitis. Table 1 shows the demographic data of the participants including sex, gestational age and birth weight of the children as well. However, a comparative analysis of the characteristic features of both groups did not show any significant differences at the baseline ($p < 0.05$). This absence of difference the grouping means that the two groups are similar, which makes it easier to explain the study results and vests the conclusions about the effectiveness of chlorhexidine in neonatal practice with credibility.

Table 1: Demographic Characteristics of Participants

Characteristic	Chlorhexidine Group (n=100)	Control Group (n=100)	p-value
Male	55 (55%)	50 (50%)	0.635
Female	45 (45%)	50 (50%)	0.635
Mean Gestational Age (weeks)	37.5 ± 1.2	37.3 ± 1.1	0.213
Mean Birth Weight (kg)	2.8 ± 0.5	2.7 ± 0.4	0.204

Comparing the omphalitis rate in each group at follow-up, the chlorhexidine group had a higher success rate of the antiseptic in shielding the umbilical area against infections. Correspondingly, omphalitis was observed in 8 neonates (8%) in the chlorhexidine arm and in 24 neonates (24%) in the control arm. Such a significant difference gave the chlorhexidine group's RR of 66.67%, which indicates a good protection from omphalitis. A similar trend was observed when the statistical analysis was being carried out and the results which indicated that the difference between the groups was statistically significant at $p < 0.01$ supported the finding. The outcome of this study is summarized in the subsequent table to commend the findings on the reduction of omphalitis incidence by chlorhexidine among the participants as shown in table 2 below. All this evidence provides compelling rationale that has informed the need to make use of chlorhexidine as an essential preventive intervention in neonatal care.

Table 2: Incidence of Omphalitis in Both Groups

Group	# of Omphalitis Cases	Total Participants	Incidence Rate (%)	p-value
Chlorhexidine	8	100	8	<0.01
Control	24	100	24	

Comparing the severity of symptoms of omphalitis in both groups showed that chlorhexidine group had less severe symptoms than the non- chlorhexidine group. In the chlorhexidine group 13 neonates developed omphalitis, out of them mean severity score was 2.1 on a scale of 1 to 5 with 1 being mild omphalitis and 5 being severe omphalitis. On the other hand, it was found that the control group indeed recorded a higher mean severity of 3.5($p < 0.01$). This significant difference points toward the preventive potential of chlorhexidine not only for decreasing the rate of omphalitis but also for minimizing the disease process when it occurs. These results are presented in table 3 where we get a clear picture of the scores given to the severity of the symptoms of the two groups.

Table 3: Severity of Omphalitis Symptoms

Group	Mean Severity Score (1-5)	p-value
Chlorhexidine	2.1	<0.01
Control	3.5	

Besides the omphalitis rate, the chlorhexidine group also had sepsis with 2 cases only (2%) compared to the 6 cases of sepsis (6%) in the control group with the p= 0.08. This would also indicate that chlorhexidine not only decreased omphalitis risk but also has a systemic protective impact. Collectively, these presented findings demonstrate the effectiveness of a single application of chlorhexidine in halting omphalitis and possibly enhancing perinatal health.

Discussion: This present study aimed at assessing the efficacy of a single pretreatment of chlorhexidine in the prevention of omphalitis in neonates, and thereby relating significant findings to neonatal management practices. It becomes clear from this study that use of 4 per cent chlorhexidine decreases the rate of omphalitis compared with conventional practice. In particular, use of chlorhexidine solution clipped with gauze resulted in the omphalitis incidence of 8% vs. 24% of the control group, that proves that risk reduction is 66.67 % ($p < .01$). This large gap proves that chlorhexidine is a critical, low-cost measure in the care of newborns.

New-born omphalitis is a significant factor that affects health of new-born because this disease deals with infections originating at umbilical stump and can be a huge issue where strict (during new-born operations) can be less stringently followed. The present research is in line with other research studies, which had established that chlorhexidine does function effectively in the inhibition of omphalitis. For example, Ishaq et al. (2020) found one study which had found that the utilization of chlorhexidine was more effective in avoiding umbilical cord infections in newborns than with basic care practices (5). Likewise, Zhou et al. (2022) did a systematic review that was also able to enlighten use of chlorhexidine in reducing healthcare associated infections in neonates and reaffirmed our recommendation (10).

In our study, we noted that while chlorhexidine worked at lowering the occurrence rate of omphalitis, it also seemed to lessen the extent of the condition among the babies who developed it. The evaluation of symptoms and signs of omphalitis by severity score revealed that chlorhexidine group was mild 2.1 as compared with control group 3.5($p<0.01$). This study's implication is that chlorhexidine emulates the risk of infection as well as reduces the severity of clinical manifestations. Such outcomes are important to be addressed, because severe omphalitis can lead to the development of systemic infections and increased morbidity hence the call for tight preventive measures in neonatal section.

Further, the lower sepsis rate recorded among the chlorhexidine group (2% as compared to 6% of the control group) show administrative applicability of chlorhexidine in more protection against systemic infections. Despite the fact that this difference was not statistically significant ($p = 0.08$) it is in agreement with other data on use of chlorhexidine as an antiseptic. Similar findings were also demonstrated by Akhtar et al. (2023) where chlorhexidine use was proved to reduced sepsis rate and overall newborn clinical deterioration (3). The implications of these findings to practical interventions are immense, especially in areas with high rates of neonatal mortality where averting neonatal infection is likely to vastly contribute to declines in mortality.

Some of the insights of this study that would make it robust include randomized controlled method used in the study reduces bias hence increases the reliability of the study. The advantage of using this methodological approach is that it makes it possible to draw a direct comparison between the chlorhexidine group of patients and control group of patients, and thus linking the application of the antiseptic directly to observed outcomes. The brushing regime using chlorhexidine was done precisely by qualified personnel to all participants, thus making for a validity of the intervention. Moreover, the study took place in a tertiary care hospital and this meant that the neonates could be observed closely. This setting allowed the disease to generate the appropriate clinical manifestations, thereby helping to maintain the accuracy of data collection, promote strict follow-up and early detection of any complications and reaffirmed the clinical application of the study.

But some of them should be provided. First, the study was performed in a single center, and it is important to cautious to generalize the results in other healthcare settings especially in rural or underprivileged setting. It would be useful for this study to continue on in larger scale multicenter formats in the future to replicate these findings in different populations across different settings. Second, while we investigated only the direct consequences of omphalitis, actions taken during follow

up were not discussed in this study. In future studies, one should investigate the impact of chlorhexidine application on neonate cumulative health, positive developmental effects, potential ill effects generating occasions.

In addition, the research should also investigate the feasibility of using chlorhexidine for song and dance associated with umbilical cord care. In some cultures, practices of their tradition are observed, and where the use of antiseptics such as chlorhexidine is new, education will have to be done to fit new styles while at the same time noting that infection prevention is important. Owing to the results of the study involving families in the care process and educating them on the appropriate use of chlorhexidine could help improve the implementation of these interventions.

CONCLUSION

This study proves that the rate of omphalitis has decreased in neonates that received only one application of 4% chlorhexidine than those who only were given standard care in cord care. The analysis here reveals that the cases of omphalitis have reduced by 66.67% relative risk reduction and that chlorhexidine may further explain less severe clinical manifestations of the affected infants. Moreover, the observed reduced rate of sepsis in the chlorhexidine group may suggest even more extensive antimicrobial activity of this agent. Since neonatal infections are a major cause of morbidity and mortality worldwide, especially in developing countries, the use of chlorhexidine in umbilical cord care is considered best practice. These findings should be replicated by other multicenter trials to validate these findings and investigate the long-term consequences of chlorhexidine use for neonatal endpoints to strengthen recommendations that enhance the overall direction of care of newborns to taxi neonatal disease and mortality.

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