

COMPARISON OF OMPHALITIS WITH APPLICATION OF CHLORHEXIDINE AND DRY CORD CARE

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Abstract

Background: Umbilical cord infection (omphalitis) is a risk factor for neonatal sepsis and mortality in low-resource settings where home deliveries are common. Up to half of neonatal deaths in high mortality settings are due to infections, many of which can originate through the freshly cut umbilical cord stump.

Objective: To compare the frequency of omphalitis with application of chlorhexidine on umbilical cord and dry cord care in neonates

Methods: This randomized controlled trial was conducted in the vaccination center of the Department of Pediatrics, Mayo Hospital, Lahore and Neonatal Unit of Lady Willingdon Hospital Lahore in 6 months duration. A total of 100 neonates were enrolled in this study. The neonates in case group got an application of the 7% chlorhexidine digluconate gel (delivering 4% chlorhexidine) on cord stump on their first day of life. Guardians or mother of the neonates in control group were advised to keep the cord stump of their neonates dry and clean without applying anything on it. They were called for follow up on 14th day of life and signs of omphalitis were noted. The data were entered and analyzed by using SPSS v23.0. Data were stratified for gestational age, gender and birth weight to address the effect modifiers. Post stratification, Chi-square test was applied to check the significance with p -value ≤ 0.05 as significant.

Results: Total 100 neonates were enrolled in this study. Neonates were divided in two groups i.e. Group-A (Chlorhexidine) and Group-B (Dry care). In group-A, 6(12%) neonates had omphalitis and in group-B, 14(28%) had omphalitis. By applying Chi-Square test, it was concluded that, there was significant difference between both groups and omphalitis ($p > 0.046$). Omphalitis was more present in Group-B as compared to Group-A.

Conclusion: Application of chlorhexidine to the umbilical cord was effective in reducing the risk of omphalitis and neonatal mortality in rural Pakistan. Provision of chlorhexidine in birth kits might be a useful strategy for the prevention of neonatal mortality in high-mortality settings.

Introduction

Neonatal mortality is a major component of under-five childhood deaths (USMR) in developing countries. About one third of annual global neonatal deaths are caused by infections alone¹. Tracking of bacteria along the umbilical vessels in newly cut umbilical cord may lead to septicaemia that can result in neonatal morbidity and mortality, especially in developing countries². Pakistan has a high neonatal mortality rate of 53 per 1000 live births with sepsis as its major contributor³. Unhygienic practices are prevalent in rural areas of the country. These include cutting the umbilical cord with household knife, and applying unsafe substances like ash, crushed lead ore called surma, oil, turmeric and even cow dung. This leads to high incidence of neonatal infections and deaths⁴.

Chlorhexidine is safe and inexpensive antiseptic and requires minimal training and skill and should strongly be considered for adoption wherever home births occur⁵. Studies have shown that chlorhexidine reduces cord colonization with pathogens and thus omphalitis and sepsis. A trial conducted by Sajid Soofi et al., in rural Pakistan showed that the rate of omphalitis was 3.2% with chlorhexidine while 7.6% without chlorhexidine (dry cord). The factorial analysis indicated a reduction in risk of omphalitis with chlorhexidine application (risk ratio [RR]=0.58, 95% CI 0.41-0.82; p=0.002)⁶. El Arifeen et al., supported the evidence and reported that the rate of omphalitis was 18.5% with chlorhexidine while 22.6% without chlorhexidine (dry cord). The difference was significant (p<0.005).⁷ Imdad A et al., observed that, chlorhexidine application on cord stump showed a reduction in omphalitis ranged from 27% to 56% depending on the severity of the infection compared to dry care cord⁷. Gathwala et al in North India showed that, chlorhexidine reduces neonatal sepsis in NICU when used on umbilical cord⁸.

This study was planned to compare the frequency of omphalitis with application of chlorhexidine in neonates compared to dry cord care. Omphalitis is a deadly infection of umbilical cord and causes significant morbidity and mortality both historically and in areas where health care is less readily available.

Through this study, we can generate local evidence about use of chlorhexidine in reducing omphalitis.

Material and Methods

This randomized controlled trial conducted in the vaccination center of the Department of Pediatrics, Mayo Hospital, Lahore and Neonatal Unit of Lady Willingdon Hospital Lahore in 6 months duration. Ethical approval was taken from King Edward Medical University, Lahore. We hypothesized that there is a difference of frequency of omphalitis with chlorhexidine application in neonates compared to dry cord care. A total of 100 neonates were enrolled in this study by non-probability consecutive sampling. (Sample size of 100 patients (50 patients in each group) was estimated by 95% confidence level with 80% power of test and taking expected percentage of omphalitis as 3.2%⁶ with Chlorhexidine application and 22.6%⁷ in dry cord care). Neonates of both genders born in lady Willingdon Hospital Lahore and are discharged on their first day of life from nursery were included. Neonates admitted in the neonatal section of a health facility, Neonates with obvious anomalies of cord or congenital defects (on clinical examination), Neonates having obvious morbidity at birth like birth asphyxia, poor Apgar score <7 at 5 minutes after birth (on clinical examination), Pre-term babies <28 weeks (as per date scan) and very low birth weight babies <1.5 kg (as recorded by routine weight machine) were excluded. Neonates were randomly allocated in two groups by using lottery method. The neonates in case group got an application of the 7% chlorhexidine digluconate gel (delivering 4% chlorhexidine) on cord stump on their first day of life by the researcher and their mothers were trained to do so once daily for first week of life. Guardians or mother of the neonates in control group was advised to keep the cord stump of their neonates dry and clean without applying anything on it. They were called for follow up on 14th day of life and signs of omphalitis were noted according to operational definition. Omphalitis was defined as the presence of redness, swelling (edema) and pus formation (any one or more) either on the cord stump or the skin at the base of stump on clinical

examination which was done on 14th day of experimental work. Neonates who developed omphalitis, was managed as per hospital protocol. The data were collected by researcher himself in a predesigned proforma.

Data were entered and analyzed by SPSS v23.0. Quantitative variables like gestational age and weight of baby were presented as Mean±S.D. Qualitative variables like gender and omphalitis were presented as frequencies and percentages. Both groups were compared for omphalitis by using chi-square test taking p-value <0.05 as significant. Data were stratified for gender, gestational age and birth weight to deal with effect modifiers. Post-stratification, Chi-Square test was applied. P-value <0.05 was considered significant.

Results

Total 100 neonates were enrolled in this study. Neonates were divided in two groups i.e. Group-A (Chlorhexidine) and Group-B (Dry care).

The mean gestational age of neonates in group A was 34.72±1.95 weeks and in group B was 35.16±2.31 weeks. Mean birth weight of neonates in group A was 2.04±0.92 kg and in group B was 1.84±0.81 kg. In group-A, 32(64%) neonates were male and 18(36%) were female. In group-B, 28(56%) neonates were male and 22(44%) were female. In group-A, 37(74%) neonates had gestational age <36 weeks and 13(26%) had gestational age >36 weeks. In group-B, 32(64%) neonates had gestational age <36 weeks and 18(36%) had gestational age >36 weeks. In group-A, 28(56%) neonates had birth weight <2 kg and 22(44%) had birth weight >2 kg. In group-B, 37(74%) neonates had birth weight <2 kg and 13(26%) had birth weight >2 kg.

In group-A, 6(12%) neonates had omphalitis and in group-B, 14(28%) had omphalitis. (Table 1). By applying Chi-Square test, there was significant difference between both groups and omphalitis (p>0.046). Omphalitis was more present in Group-B as compared to Group-A. (Table 2-4)

Table-1: Frequency distribution of Omphalitis in both groups

Groups	Omphalitis	N (%)	Percent
Chlorhexidine	Present	6 (12)	12.0
	Absent	44 (88)	88.0
	Total	50	100.0
Dry Care	Present	14 (28)	28.0
	Absent	36 (72)	72.0
	Total	50	100.0

Table-2: Comparison between Omphalitis and Groups

Groups	Omphalitis		Total	p-value Chi-Square test
	Present	Absent		
Chlorhexidine	6	44	50	0.046
	12.0%	88.0%	100.0%	
Dry Care	14	36	50	
	28.0%	72.0%	100.0%	
Total	20	80	100	
	20.0%	80.0%	100.0%	

Table-3: Stratification of Omphalitis with respect to Gender in both groups

Groups	Gender	Omphalitis		Total	p-value Chi-Square test
		Present	Absent		
Chlorhexidine	Male	1	31	32	0.010
		3.1%	96.9%	100.0%	
	Female	5	13	18	

		27.8%	72.2%	100.0%	
	Total	6	44	50	
		12.0%	88.0%	100.0%	
Dry Care	Male	7	21	28	0.594
		25.0%	75.0%	100.0%	
	Female	7	15	22	
		31.8%	68.2%	100.0%	
	Total	14	36	50	
		28.0%	72.0%	100.0%	

Table-4: Stratification of Omphalitis with respect to Gestation age in both groups

Groups	Gestational Age Groups	Omphalitis		Total	p-value
		Present	Absent		
Chlorhexidine	<36 weeks	3	34	37	0.153
		8.1%	91.9%	100.0%	
	>36 weeks	3	10	13	
		23.1%	76.9%	100.0%	
Total	6	44	50		
		12.0%	88.0%	100.0%	
Dry Care	<36 weeks	10	22	32	0.495
		31.3%	68.8%	100.0%	
	>36 weeks	4	14	18	
		22.2%	77.8%	100.0%	
Total	14	36	50		
		28.0%	72.0%	100.0%	

Table-5: Stratification of Omphalitis with respect to Birth weight in both groups

Groups	Birth Weight Groups	Omphalitis		Total	p-value
		Present	Absent		
Chlorhexidine	<2 kg	4	24	28	0.575
		14.3%	85.7%	100.0%	
	>2 kg	2	20	22	
		9.1%	90.9%	100.0%	
Total	6	44	50		
		12.0%	88.0%	100.0%	
Dry Care	<2 kg	11	26	37	0.646
		29.7%	70.3%	100.0%	
	>2 kg	3	10	13	
		23.1%	76.9%	100.0%	
Total	14	36	50		
		28.0%	72.0%	100.0%	

Discussion

Our observations suggest superiority of the chlorhexidine application over conventional dry care in the context of neonatal umbilical cord care. Omphalitis in chlorhexidine group (12%) was less than in the control group (28%). There was a significantly decreased incidence of blood culture-proven sepsis among the

newborns in the intervention group though there was statistical significant difference noted among the groups with regards to umbilical infection ($p > 0.046$). Our findings suggest the role of chlorhexidine local application as a simple, affordable and easily available intervention for prevention of culture-proven neonatal sepsis in a resource-poor setting;

however, slight caution is advised while generalizing our result to the population at large. In Germany, Kapellen et al.⁹ conducted randomized controlled study to compare efficacy and safety of chlorhexidine (CX) powder versus dry care (DC) in umbilical cord care of newborn.

The Omphalitis in chlorhexidine group (15%) was less than in the control group (35%) $p < 0.001$. The mean difference between the two treatment groups was for umbilical cord separation 18.9 hours. Studies have shown that chlorhexidine reduces cord colonization with pathogens and thus omphalitis and sepsis. A trial conducted by Sajid Soofi et al., in rural Pakistan showed that the rate of omphalitis was 3.2% with chlorhexidine while 7.6% without chlorhexidine (dry cord). The factorial analysis indicated a reduction in risk of omphalitis with chlorhexidine application (risk ratio [RR]=0.58, 95% CI 0.41-0.82; $p=0.002$).⁶ El Arifeen et al., supported the evidence and reported that the rate of omphalitis was 18.5% with chlorhexidine while 22.6% without chlorhexidine (dry cord). The difference was significant ($p < 0.005$).⁷ Imdad A et al., observed that, chlorhexidine application on cord stump showed a reduction in omphalitis ranged from 27% to 56% depending on the severity of the infection compared to dry care cord.⁵ Gathwala et al in North India showed that, chlorhexidine reduces neonatal sepsis in NICU when used on umbilical cord.⁸ In a hospital-based study from Pakistan, evaluating the impact of daily cord cleansing, it was observed that omphalitis occurred less in chlorhexidine group.⁴

In a community-based cluster randomized trial in Sylhet, Bangladesh, about impact of 4% chlorhexidine cleansing of umbilical cord on omphalitis and mortality, it was observed that immediate (day 1) reductions in cord colonization were observed in single (RR=0.75, 95% CI: 0.70-0.81) and multiple (RR=0.71 [0.66- 0.77]) cleansing groups. Multiple cleansing also showed reduced colonization by invasive organisms on 3rd and 6th days of application.¹⁰ Sinha et al.¹¹ observed protective role of chlorhexidine in cord care. The use of chlorhexidine for umbilical cord care has been reported to be safe by several authors.¹² In the index study too, no adverse effects were

observed with the use of chlorhexidine umbilical cord care.

This study has certain limitations. The subjects in our study were delivered and managed at a tertiary care referral setting with a distinguished setting of microbiological flora, exposures to interventions, availability of equipments, procedures and protocols, considerably different from a usual community neonatal care setting. Therefore, the results of this study can be extrapolated only to neonates admitted to a NICU. A larger community-based study can possibly provide better insight into the role of this intervention in that context.

Conclusion

Application of chlorhexidine to the umbilical cord was effective in reducing the risk of omphalitis and neonatal mortality in rural Pakistan. Provision of chlorhexidine in birth kits might be a useful strategy for the prevention of neonatal mortality in high-mortality settings.

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