

Efficacy of 4% chlorhexidine in preventing neonatal umbilical cord infection

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ABSTRACT

Background: Umbilical cord stump is a budding point for bacterial colonization subsequently leading to sepsis that contributes to high neonatal morbidity and mortality, if not properly managed. Antiseptic care can significantly reduce omphalitis and ultimately improve newborn survival. Objective of this study was to see the efficacy of 4% chlorhexidine use to prevent umbilical cord infection in neonates.

Subjects and methods: It was a comparative analytical study conducted in Neonatal unit, Sir Ganga Ram Hospital (SGRH) Lahore from July, 2016 till January, 2017. One hundred neonates were enrolled and randomized into two equal group by simple random method (50 each). In one group, nothing was applied to cord while in chlorhexidine group, 4% chlorhexidine gel was applied on umbilicus and around it, once daily for 7 days or till cord detached whichever came early. First application was done by a nurse followed by duly trained mother/caregiver. The signs of omphalitis (redness, pus or localized oedema) were observed and recorded for each neonate in both groups. Chi square test was used to see the difference in omphalitis in these groups with $p < 0.05$ considered as statistically significant result.

Results: Out of 100 neonates, 29 (58%) and 23 (46%) males while 21 (42%) and 27 (54%) females neonates belonged to dry care and chlorhexidine group respectively. Nineteen (38%) neonates with dry cord had omphalitis compared to only 5 (10%) in chlorhexidine group ($p 0.001$). Neonates with chlorhexidine application showed prolonged mean cord separation time (7.9 ± 1.5 days) compared to dry care (6.1 ± 1.8 days).

Conclusion: The use of 4% Chlorhexidine was effective to lower omphalitis compared to neonates with dry cord care.

Keywords:

Umbilical cord; Chlorhexidine; Dry cord, Omphalitis; Prevention

INTRODUCTION

Globally more than 1 million neonatal deaths are attributed to infections.^{1,2} One of the common site of infection is umbilical stump which is tied and cut after birth. It detaches in 7-10 days.³ In poor socio economic settings, the omphalitis is reported upto 8% in hospital born infants while to the extent of 22% in home deliveries⁴. Unhygienic cord care practices are prevalent in community settings. People are still using traditional substances like turmeric, ash, surma, powder, mustard oil and various other agents for cord care.⁵ At health facility, a variety of local antiseptics are being practiced including alcohol, antibiotic ointment, povidone-iodine, triple dye, soap and water or no treatment at all and none of these have proven superior in limiting sepsis.⁶ Currently umbilical cord care practices vary in different

regions within a country and no uniform protocol is being followed so far. Similar finding have been reported by a research carried out in Pakistan.⁷ Community level trials in Nepal, Bangladesh and Pakistan showed reduced mortality from all causes by 23% and decline in umbilical infection ranged from 27-54% with 4% chlorhexidine application.⁸⁻¹⁰ These trials and other research work proved that chlorhexidine is easy to use, practicable and cost effective worthwhile intervention in newborn care.⁸⁻¹² Chlorhexidine is a broad-spectrum antiseptic effective against gram positive and negative bacteria, fungi and demonstrates antiviral properties in vitro.¹³ World Health Organization (WHO) has given recommendation after reviewing evidence that in areas where newborn are delivered at home and have high mortality rates, 4% chlorhexidine should be applied at umbilical cord immediately after birth and during first 7 days of life.¹⁴

The rationale of this study was to determine the efficacy of chlorhexidine use to prevent neonatal umbilical infection. Present study was carried out so that its results may emphasize the use of chlorhexidine

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as a preventive tool in maternity amenities where hygiene conditions are doubtful or where mothers and newborns are typically discharged within few hours of delivery, increasing the probability that a newborn may be vulnerable to perilous circumstances during this early exposure window.

SUBJECTS AND METHODS

It was a comparative study conducted in Neonatal unit of Paediatrics Department, Sir Ganga Ram Hospital (SGRH), Lahore from July, 2016 till January, 2017. Sample size of 100 neonates was designed by using formula with expected reference values.¹⁸ We used 95.0% confidence level and 80% power of study. All live new borns delivered in the hospital setting of SGRH weighing >1.5 kg born at >32 weeks gestation age (from first date of last menstrual period) were recruited by non-probability sampling technique. Neonates with septicaemia (blood culture >10 bacteria/HPF), severe asphyxia (APGAR score <3 at 5 minutes), critically sick on ventilators, umbilical cord defects (hernia or omphalocele), other congenital anomalies and those who require umbilical vein catheterization were excluded.

After permission from the hospital Institutional Ethics Review Board, written informed consent was also taken from parents/guardians who agreed to participate in this study. A total of 100 cases fulfilling the inclusion and exclusion criteria were randomized into two equal groups by simple random method, 50 to dry cord care and 50 to chlorhexidine group. Dry cord care was considered if umbilical cord was allowed to dry and falls on its own without applying any substance on it. In chlorhexidine group, 4% chlorhexidine gel was applied once daily on umbilical stump and area around it, for seven days or till umbilical cord separated whichever came early. First application was done by a nurse followed by duly trained mother/caregiver. Umbilical cord examination was performed by doctor on alternate days for signs of omphalitis till it fell off and noted down on data collection form for every neonate in both groups. In chlorhexidine group, babies were also monitored for any side effect of chlorhexidine. Omphalitis was labelled if one or more of these signs or symptoms were observed in neonates; purulent discharge present at umbilical stump, periumbilical erythema or oedema. According to severity of clinical signs, omphalitis was classified into mild (only pus, redness/ swelling of the cord stump), moderate (when purulent discharge, swelling or redness is beyond

umbilical stump, <2 cm of skin of abdomen around stump) and severe (when inflammation signs involve skin >2 cm around stump). Those who discharged early were called for follow up on alternate days until umbilical cord fell off and their parents were told about diaper to fold below the umbilical cord. They were also counselled regarding danger signs of umbilical cord infection like redness, swelling or purulent discharge from umbilical stump, as well as side effects of chlorhexidine application (although very rare like mild skin redness or hypersensitivity reaction) on discharge and if subjects developed any of the above mentioned features, mothers were advised to return immediately for follow up advice.

The data was entered and analysed using SPSS version 18. All qualitative data like gender and omphalitis was presented in the form of frequency (%). The quantitative variables like gestational age and birth weight were presented in form of mean \pm SD. Impact of chlorhexidine use was measured in terms of its efficacy to prevent umbilical infection so difference in omphalitis was done by using chi square test while mean cord separation time was compared between two groups with independent t-test. A p value <0.05 was considered significant.

RESULTS

A total of 100 neonates were enrolled that included 29 (58%) and 23 (46%) males while 21 (42%) and 27 (54%) were female in dry care and chlorhexidine group, respectively. Demographic variables were comparable in both groups as mentioned in Table 1. Regarding gestational age, 25 (50%) in dry care and 22 (44%) subjects in chlorhexidine group born between 32-37 weeks of gestation whereas 25 (50%) and 28 (56%) were between > 37-40 weeks of gestation respectively. Omphalitis was observed in 19 neonates (38%) in dry care (Table 1). Among these only 4 babies had moderate omphalitis while 15 were with mild signs of umbilical cord infection. In chlorhexidine group, 5 (10%) developed clinical signs of mild omphalitis. None of these had severe sign of cord infection. A p-value (0.001) showed a significant difference in these two groups. No side effect was observed in any neonate in chlorhexidine group. Time recorded for cord separation was 7.9 \pm 1.5 days in chlorhexidine group while it was 6.1 \pm 1.8 days in those who received dry care. A significant difference (p<0.0001) was observed in mean cord separation time as chlorhexidine group took longer detachment time compared to other group.

Table 1. Demographic characteristics and comparison of frequency of omphalitis by applying Chlorhexidine versus dry cord care

Characteristics	Dry cord care n (%)	Chlorhexidine n (%)	p-value
Mean gestational age (weeks [mean±SD])	36.5±1.7	37.0±3.0	0.3084
Mean birth weight (g [mean±SD])	2500±450	2600±300	0.1946
Gender			
Male	29 (58%)	23 (46%)	0.2298
Female	21 (42%)	27 (54%)	
Omphalitis	19 (38%)	5 (10%)	0.001

DISCUSSION

Due to insufficient data in favour or against topical application of an antiseptic, dry cord care has been recommended by WHO till 2012. On the basis of moderate quality evidence WHO revised cord care guidelines in late 2013 and recommend that in order to avoid harmful practices of cord care, it is very suitable to apply chlorhexidine for home births in high mortality settings. There was 75 % less omphalitis cases in chlorhexidine group in a study conducted in Nepal.⁸ A study from Kerala reported that frequency of omphalitis was 44% in babies provided with dry care than 6.5 % with chlorhexidine application.¹⁵ The United Nations Commission on Life-Saving Commodities (UNCoLSC) identified chlorhexidine as lifesaving drug for skin and umbilical cord care for women and children in 2012 and included it one of thirteen essential commodities.¹⁶ Chlorhexidine has encouraging efficacy and less side effects in comparison to other antiseptics and is low cost.¹⁷ Demographic characteristics of this study population were comparable in both groups. Omphalitis was found remarkably low in chlorhexidine group (10%) paralleled to those where nothing applied on cord (p=0.001). This finding was comparable with an Indian study carried out in a hospital setting revealed culture proven sepsis was higher (21.43%) in the dry care participants than receiving chlorhexidine (2.86%).¹⁸ A systematic review with meta-analysis performed by Lopez-Medina and co-workers from 9 eligible studies (118,903 NB in total) showed 64.03% of omphalitis cases belonged to the dry cord care group.¹⁹ This research concluded that in high NMR (>10 deaths per 1000 live births) countries, 4% chlorhexidine application significantly protect against omphalitis in home births with inappropriate hygienic conditions and reinforced its use in developing countries. Whereas, in countries with less NMR, two types of cord care did not reveal any difference in preventing omphalitis. Another Cochrane data base of systemic reviews reported high quality evidence about chlorhexidine use for cord cleansing resulted in 50% and 12% reduction in omphalitis incidence and NMR respectively in community setting.²⁰ Similar results have been found by Roba and colleagues that it decreased the omphalitis

incidence by 35% in low income countries.²¹ Contrary to our result a study by Riaz and coauthors in Rawalpindi hospital found no significant difference in term of umbilical cord infection between two cord care methods.²² In this study, in chlorhexidine group cord was separated late (7.9±1.5 days) than those whose cord was kept dry (6.1±1.8 days). Similar significant difference (p=0.003) was observed by a study carried out in a previous study.²² In contrast another study from Pakistan recorded no difference in mean duration of separation of umbilical cord between two groups in rural district although risk of omphalitis was lower in chlorhexidine group than controls.¹⁰ Results of current study markedly differ from those of Gathwala and coresearchers who noted shorter cord separation time in chlorhexidine versus dry cord care group (8.92±2.77 versus 10.31±3.23 days).¹⁸

An important consideration regarding the time of umbilical cord detachment should be taken into account as this point is mostly emphasized in developed areas where chances of umbilical cord infection and neonatal deaths are quite less.²³ Strategies that involve the handling of cord stump with application of topical agents may tend to prolong separation time period so may add to risk of infection in some babies but this differentiation can only be implemented in areas where possibility of infection is less.²⁴ In poor resource countries like Pakistan where chances of infections and deaths are more, an infant can be benefited from chlorhexidine application, detachment time will not affect the outcome and the mere difference of few hours does not make any negative impact on final outcome.²⁵ By applying chlorhexidine infection rate of umbilical stump is decreased as per several studies so it is recommended to apply chlorhexidine to reduce infection risk.^{21,26} Despite WHO recommendation it has yet not been introduced and practiced frequently for cord care in local community and health settings so more studies should be conducted to prove its efficacy. In this study, sample size was small and carried out in a single hospital setting so more studies should be conducted with large sample in multiple health centres and community settings to get better results.

CONCLUSION

Chlorhexidine use was effective to lower neonatal omphalitis compared to those who received dry cord care although cord detachment time was prolonged in former group. So it may be used regularly in our common practice whether in hospital settings or in home births and it should be included as standard protocol in essential new born care in our setup where NMR is quite high.

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