



**A NON RANDOMIZED CONTROL STUDY ON THE EFFECTIVENESS OF THE
TWO METHODS: DRY CORD CARE AND 4% CHLORHEXIDINE ON CORD
SEPARATION TIME.**

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Abstract

Introduction: Newborns have the highest risk of death in the first 4 weeks of their life and main cause for this is infection. Umbilical cord of a child is an important site for microorganism colonization and also forms a portal of entry for invasive pathogens. To effectively complete umbilical stump separation promptly and safely without experiencing any additional issues, cord care is a crucial stage in neonatal care. Inadequate cord care can result in intra-abdominal abscesses, thrombophlebitis in the umbilical and/or portal veins, periumbilical cellulitis, peritonitis, and bowel ischemia. This study focuses on the umbilical cord separation time by 2 separate cord care regimens: dry cord care and 4% chlorhexidine care group.

Methodology: This is a non-randomized control time-bound study conducted at a tertiary health care centre, government lady goschen hospital, Mangalore, Dakshina Kannada District, Karnataka. A total of 144 newborns fulfilling the inclusion criteria were included and then divided randomly into two groups: dry cord care and 4% chlorhexidine. Post discharge the newborns were followed up by phone call to know the time of umbilical stump separation and to enquire about health of the umbilical stump. Results were evaluated with Chi-Square test and Karl Pearson correlation analysis.

Results: Cord separation time was more common between day 5 to day 9 of life in chlorhexidine group (n= 50/72) and it was between day 4 to day 7 of life in dry cord care group (n=62/72). In chlorhexidine group, 2 newborn had cord separation time more than 14 days of life. Mean cord separation time was 7.7 (3.2) days in chlorhexidine and 5.68 (1.9) days in dry cord care group.

Conclusion: There was delay in cord separation time in chlorhexidine group in comparison to dry cord care group.

Key words: 4% chlorhexidine, cord care, separation time.

INTRODUCTION

The connection between a child and the placenta of the uterus is the umbilical cord. This cord is covered with membrane bathed with amniotic fluid and is made up of blood vessels and connective tissues. After the child birth this cord is separated from placenta physically. Umbilical cord is an important site for bacterial colonization leading to cord stump infection and this infection is known as omphalitis. This omphalitis develops on an average around third or fourth day of life of a newborn and may be present approximately upto 20 days of age which can be a serious condition and cause septicaemia [1, 2]. This risk of infection increases till the umbilical cord is detached. World Health Organisation (WHO) estimates that out of total deaths in infants occurring in first week of life, nearly 75% is caused due to umbilical cord infection [3].

Infection in mother, failure in following sterilization protocol during delivery, catheterization of umbilical cord, low birth weights and inadequate cord care increases the risk of cord stump infection [4]. Therefore prevention of this risk factor can be of utmost importance especially the later seems to be most vulnerable. It is important to prevent this infection by taking proper umbilical cord care in neonatal period. While the clean method of cutting the cord with a sterile cutting tools and clean hands to prevent infection is generally accepted, there is less consensus on the best way to treat the cord stump [5,6].

To decrease the risk of neonatal morbidity and mortality and to bring down the infection arising from cord stump, WHO recommends keeping the cord clean and not to apply anything to it (dry cord care), that is, just to clean it with soap and regular water. As achieving this goal is difficult, WHO also advises the usage of topical antiseptics in settings where there is high infection risk as in case of a birth at home or where neonatal mortality rate is high [7]. A broad spectrum antiseptic that works against both gram positive and negative bacteria and also against HIV virus is chlorhexidine [8]. It is one of the most affordable and efficacious interventions in preventing infections and in improving neonatal survival in low-resource settings such as ours. Application of antiseptics for cord care has reduced instances of infection but is also associated with delayed separation of umbilical stump.

Umbilical stump usually separates within 2 weeks of life and is said to be delayed if it is more than 14 days [9, 10]. There are various factors which causes varying separation time of the cord. The cord separation after 3 weeks of life is considered to be out of range [11] and may be associated with defective mobility of neutrophils [12].

Therefore, this study aims to assess the umbilical cord separation time with dry cord care method and the intervention of application of 4% chlorhexidine.

METHODOLOGY

This is a non-randomized control time-bound study (September 2019 to September 2021) done at a Tertiary care centre, Government Lady Goschen Hospital, Mangalore, Dakshina Kannada District, Karnataka.

Inclusion criteria:

- Neonates \geq 34 weeks of gestation, hemodynamically stable and not requiring NICU care.

Exclusion criteria:

- Babies born to mother having: HIV, Hepatitis B, Active tuberculosis
- Babies born to mother with suspected septicemia: fever with rash in the mother, features of urinary tract infection, prolonged rupture of membranes (> 18hours)
- Babies by mother's side but on antibiotics.

A total of 144 newborns were considered in this study and divided into 2 groups with 72 newborns in each group with convenient sampling method. The study was initiated after seeking approval from the Institutional ethical committee (IEC KMC MLR 10-19/494), and CTRI registration (REG No: CTRI/2020/05/025266). Written consent was obtained from the parents agreeing to participate and was allocated into one of the groups by a single investigator. Parents were briefed about the objectives of the study and participant information sheets were given. In dry cord care group, the cord was cleaned with sterile gauze to clean the blood stains after birth and dried and exposed to air and parents/ caregivers were advised to wipe with gauze after bath and to tie the diaper/ cloth below the umbilical cord stump. In the intervention group, 4% chlorhexidine supplied in 10ml bottles was applied one time daily until the cord separated. Sufficient quantity of chlorhexidine was applied by the principal investigator on day 1 and thereafter, mothers were taught to apply under supervision. Mothers were taught to identify the signs and symptoms of infection of the umbilical stump. Post discharge the newborns were followed up by phone call to know the time of umbilical stump separation and to enquire about

health of the umbilical stump. If signs of umbilical infection are present parents were asked to come to the hospital for follow up and treatment.

The data was collected and coded onto excel sheet and analysed using the IBM SPSS (Statistical package for social sciences) for Windows version 25.0, Armonk, NY: IBM Corp. Continuous variables were expressed as mean and standard deviation and categorical variables were expressed as frequency and percentage. Two groups were compared using Chi square test, and Karl Pearson correlation coefficient was used to correlate the mean cord separation time. P value of <0.05 was considered as statistically significant.

RESULT

Gender of the newborns were almost equal in both the study groups with male newborns being 51.3% in chlorhexidine group and 50% in dry cord care group. Female newborns were 48.7% and 50% in chlorhexidine and dry cord care group respectively. No statistical significance with respect to gender was observed. Gestational age in both the groups were similar, with preterm neonates being 8.3% and term being 92.7%.

Average weight was 2901 (462.86) gms in chlorhexidine and 3009.44 (552.98) gms in dry cord care group. Based on the weight, 77.7% and 68% were between 2500 to 3500 gms in the chlorhexidine and dry cord care group respectively. 9% of the neonates were having less than 2500 gm in both the group. 7% and 19.4% of neonates were more than 3500 gms in chlorhexidine and dry cord care group respectively.

Data for cord separation could be collected for 112 newborn out of the overall 144 study population. 32 newborns were lost to follow up. Of the 112 newborns data collected, 84.8 % of the infants had cord separation between day 4 to day 9 of life with day 5 and 6 accounting for 20.5% and 18.8% respectively. 0.9% (n=2) had cord separation time more than 14 days of life. Mean day of cord separation time was 6.58 ± 2.73 days.

TABLE 1: DAY OF CORD SEPARATION BETWEEN THE GROUPS

		Chlorhexidine Group (50/72)	Dry cord care (62/72)	P-value*
	Day of life	n (%)	n (%)	

	3	2 (4%)	2 (3.2%)	
	4	4 (8%)	15 (24.2%)	
	5	5 (10%)	18 (29 %)	
	6	8 (16%)	13 (21%)	
	7	6 (12%)	7 (11.3%)	
	8	8 (16%)	2 (3.2%)	
	9	8 (16%)	1 (1.6%)	
	10	4 (8%)	1 (1.6%)	
	11	1 (2%)	2 (3.2%)	
	12	1 (2%)	1 (1.6%)	
	13	1 (2%)	-	
	>14	2 (4%)	-	
Mean (SD)		7.70(3.2)	5.68(1.9)	<0.001

Cord separation time was more common between day 5 to day 9 of life in chlorhexidine group (n= 50/72) and it was between day 4 to day 7 of life in dry cord care group (N=62/72). In chlorhexidine group, 2 newborns had cord separation time more than 14 days of life. Mean cord separation time was 7.7 (3.2) days in chlorhexidine and 5.68 (1.9) days in dry cord care group. Statistical significance result was noted with a P value of <0.001 with respect to cord

separation time between the two groups. There was delay in cord separation time in chlorhexidine group in comparison to dry cord care group. (Table 1)

TABLE 2: CORD SEPARATION TIME BASED ON GENDER, GESTATIONAL AGE AND WEIGHT

Category		Chlorhexidine group(n=72)			Dry cord care(n=72)		
		Days (SD)	Number	P value*	Days (SD)	Number	P Value*
Gender	Male	7.85 (3.88)	26	0.74	5.83(2.3)	30	0.53
	Female	7.54 (2.28)	24		5.53(1.31)	32	
Gestational Age	Preterm	9.2(2.38)	5	0.27	5.33(.86)	6	0.64
	Term	7.53(3.24)	45		5.71(1.96)	56	
Birth Weight (gram)	<2500	7.4(1.81)	5	0.77	5.5(1.19)	8	0.71
	2500-3500	7.7(3.49)	40		5.67(2.07)	43	
	>3500	8(1.41)	5		5.82(1.53)	11	
	Total	7.7(3.19)	50/72		5.68(1.88)	62/72	

Average weight in grams (SD) was 2901(462.86) gms in chlorhexidine and 3009.44(552.98) gms dry cord care group. Based on the weight, 77.7% and 68% were between 2500 to 3500 gms in the chlorhexidine group and dry cord care group respectively. 9% of the neonates were having less than 2500 gm in both the group . 7% and 19.4% of neonates were more than 3500 gms in chlorhexidine and dry cord care group respectively. There was no statistical significance result noted for the cord separation time within the group and between the two study groups based on the gender, gestational age and weight (Table 2)

DISCUSSION

Cord care is an essential part of neonatal care in order to successfully accomplish umbilical stump separation quickly and safely without encountering any further problems. Inadequate cord care can lead to bowel ischemia, peritonitis, periumbilical cellulitis, intra-abdominal abscesses, and thrombophlebitis in the umbilical and/or portal veins [4]. In this study, we compared 2 methods of cord care regimens: dry cord care versus topical application of 4% chlorhexidine. The use of chlorhexidine for handling umbilical cords has been recognized safe by a number of authors. According to research by other authors, the umbilical cord separates more quickly when it is dryer, which is consistent with our findings about how frequently it becomes wet. However, when the umbilical cord was moistened twice or three times each day, other researchers observed lengthier cord separation periods. In our study chlorhexidine was applied once a day until the cord separated and was similar to study conducted by Lyngdoh et al [14]. Telephonic follow up was done in our study to know the day of separation and to enquire of any symptoms of infection. Similar findings regarding birth weight were found by other authors, who indicated that cord separation time increased with increasing birth weight, but the effect size was small, as it was in our study. The time to umbilical cord separation was not significantly impacted by birth weight in certain trials, however, according to multiple regression analysis. In the pre-term infant group, other investigators have demonstrated a negative correlation between detachment time of umbilical cord and birth weight, but in term infants this correlation was not statistically significant.

Mullany et al., studied in Nepal comparing dry cord care with 4% chlorhexidine topical application to the cord and with cleansing the cord with soap and water. Omphalitis was noted 0.2 % and 1% respectively in both the groups [8].

In our study, the mean cord separation time in chlorhexidine group was 7.7 days and 5.6 days in dry cord care group. Chlorhexidine group had delayed cord separation which was statistically significant in comparison with dry cord care group. This is similar to finding in Lyngdoh et al study.(14) which showed delayed cord separation time that is 12 days in chlorhexidine group in comparison to 10 days in dry cord care group.

Study by Mullany et al(2012). (8) compared the 3 different regimens of cord care on the time of separation. Mean separation time of in this study was 4.78 days for dry cord care group and 6.9 days (difference =2.1; 95% confidence interval: 1.85-2.35) and 7.49 days (difference =

2.69; 95% confidence interval: 2.44-2.95) in single and multiple application of chlorhexidine respectively. Our study has also had similar findings.

In a study by Pezzati et al., (6) of 1470 full term infants based on 8 different cord care regimens found the mean separation time to be earliest at 5.6 days with application of salicylic sugar powder and the longest was with 70 % alcohol at 16.9 days . Mean cord separation with dry cord care in Pezzati et al study was 7.5 days.

Further studies are required to know the efficacy of topical antiseptics as part of routine cord care in low resource and high neonatal mortality settings.

CONCLUSION

4% chlorhexidine delayed the umbilical cord separation when compared with dry cord care method. Gender, gestational age and weight of the child had no effect on the separation time.

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