The Research of Medical Science Review
ISSN: 3007-1208 & 3007-1216 Volume 3, Issue 5, 2025

COMPARISON OF TIME TO CORD SEPARATION AND FREQUENCY OF OMPHALITIS IN CHLORHEXIDINE CLEANING VERSUS DRY CORD UMBILICAL CORD CARE IN NEWBORNS

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DOI: https://doi.org/10.5281/zenodo.15401047

Keywords
Chlorhexidine, Dry Cord Care, Umbilical Cord Separation, Omphalitis, Neonatal Infection, Pakistan

Article History
Received on 05 April 2025
Accepted on 05 May 2025
Published on 14 May 2025

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Abstract

Objectives: *To compare the time to cord separation and frequency of omphalitis in chlorhexidine cleaning versus dry umbilical cord care in newborns.*

Methodology: *The study was conducted at Department of Pediatrics Children Hospital and Institute of Child Health Multan from 11th December 2023 to 10th June 2024). A total of 174 neonates were randomly allocated to either the chlorhexidine group or the dry cord care group. Each neonate was followed to assess the time to cord separation and monitored for clinical signs of omphalitis. Demographic variables including gestational age, birth weight of the neonates, gender, and mode of delivery were also documented.*

Results: *A significantly longer mean cord separation time was noted in the chlorhexidine group (8.72 ± 3.55 days) than in the dry care group (6.66 ± 2.67 days) ($p < 0.001$). The incidence of omphalitis was 5.7% in the chlorhexidine group versus 3.4% in the dry care group, without statistical significance ($p = 0.469$).*

Conclusion: *Chlorhexidine delays cord separation but does not significantly reduce omphalitis compared to dry care. Dry cord care remains a safe, effective, and time-efficient alternative in hygienic hospital environments.*

INTRODUCTION

Shortly after birth, the umbilical cord stump becomes colonized by bacteria.[1] The non-viable tissue of the stump offers a favorable environment for bacterial proliferation, while the umbilical vessels serve as a direct pathway into the neonate's bloodstream.[2] These bacteria can penetrate the necrotic stump and travel through the blood vessels or surrounding connective tissue, leading to phlebitis or arteritis.[3] The infection may then extend to the surrounding periumbilical tissues or disseminate to distant organs via embolic spread.

Reported incidence rates of umbilical infections vary widely across published studies.[4] Current guidelines emphasize the importance of clean cord care and maintaining dryness.[5] The use of antiseptic powders remains uncertain, as clear evidence of their benefit

is lacking. WHO guidelines primarily target resource-limited settings; however, in hospital environments such as nurseries or neonatal intensive care units, the use of topical antimicrobial agents is advised.[6] A Cochrane Review has concluded that maintaining cord hygiene alone is just as safe and effective as using antibiotics or antiseptics.[7] Many care protocols use time to cord separation (TCS) as the primary outcome measure. However, numerous studies have also examined how various cord care practices influence the development of omphalitis or systemic bacterial infections.[8] Chlorhexidine (CX), a broad-spectrum antiseptic, is widely utilized due to its efficacy against a range of gram-positive and gram-negative bacteria. Its use for skin antisepsis is supported by several clinical guidelines.[9]

In a study by Kapellen TM et al., 669 neonates were assigned to either chlorhexidine (n = 337) or dry cord care (n = 332). The chlorhexidine group had a significantly shorter mean cord separation time (7.0 ± 2.5 days) than the dry care group (7.8 ± 2.9 days; $p < 0.001$). Omphalitis occurred in 2 cases with chlorhexidine and 7 with dry care, a difference that was not statistically significant ($p = 0.1$). Rates of umbilical granuloma were similar in both groups.[10]

In a randomized trial by Riaz N et al., 200 neonates were evenly divided into two groups. The chlorhexidine group had a mean cord separation time of 8.35 ± 3.73 days, while the dry care group showed 6.98 ± 2.59 days ($p = 0.003$). Infection was noted in 5% of neonates with chlorhexidine and 4% with dry care ($p = 0.73$).[11]

In light of unsatisfactory antiseptic practices in our region, we initiated this study to evaluate the effectiveness of chlorhexidine versus dry cord care for umbilical cord management. The outcomes are expected to contribute to evidence-based recommendations tailored to our local healthcare setting.

METHODOLOGY:

After obtaining approval from the Institutional Ethics Review Committee (*No=2148/CH&UH Multan Dated: 29-11-2023)* and synopsis approval from CPSP this study was undertaken over six months at Department of Pediatrics Children Hospital and Institute of Child Health Multan from 11th December 2023 to 10th June 2024) with 174 neonates enrolled using a non-probability consecutive sampling method. Sample size was calculated using OpenEpi software for comparison of means, based on the assumption of a mean cord separation time of 8.35 ± 3.73 days in the chlorhexidine group and 6.98 ± 2.59 days in the dry care group, with 80% power and a 95% confidence level. Eligible participants included neonates within 24 hours of birth, with gestational age between 37 and 42 weeks, birth weight greater than 2.5 kg, of either gender, admitted for feeding establishment or respiratory support. Exclusion criteria were neonates requiring umbilical catheterization, those with congenital malformations, or those born to mothers with signs of infection, including maternal fever or prolonged rupture of membranes exceeding 24 hours.

Once parental written consent was secured, key demographic information such as gestational age, gender, mode of delivery and birth weight was collected for each neonate. Study design was randomized controlled trial so the neonates were then randomly allocated into two groups via sealed opaque envelopes: Group A received chlorhexidine for cord care, and Group B followed a dry cord care regimen.

In Group A, chlorhexidine 4% solution was applied to the umbilical stump and base three times daily (once per nursing shift), continuing until three days after the cord had separated. In Group B, the umbilical cord was kept dry and clean, with diapers folded below the stump to avoid irritation. The stump was inspected twice daily for signs of omphalitis during hospital stay and by parents after discharge. Parents were instructed to continue the assigned cord care practice at home until three days post cord separation.

Outcome measures included time to cord separation (in days) and occurrence of omphalitis, defined as the presence of periumbilical redness, induration, or discharge. Data were documented on a predesigned proforma.

Using SPSS version 23, the dataset was subjected to descriptive and inferential statistical analysis. The Shapiro-Wilk test determined the normality of continuous variables. Mean and standard deviation were calculated for birth weight, gestational age, and cord separation duration. Frequencies and

percentages were reported for gender, delivery mode, and omphalitis. Intergroup comparisons for cord separation time utilized the independent samples t-test, and the chi-square test was used for omphalitis frequency. Stratification was conducted across key variables, and post-stratification comparisons were made using the same respective tests.

RESULTS:

Demographic Characteristics

Table 1 presents the distribution of gender and mode of delivery among the two intervention groups: chlorhexidine and dry cord care. In the chlorhexidine group, 42 out of 87 neonates (48.3%) were male, and 45 (51.7%) were female. Similarly, the dry cord care group comprised 40 males (46.0%) and 47 females (54.0%). Among the 174 neonates enrolled, gender distribution was nearly equal, with a slight female predominance (52.9% vs. 47.1%). Regarding the mode of delivery, the majority of neonates in both groups were born via spontaneous vaginal delivery (SVD). In the chlorhexidine group, 66 neonates (75.9%) were delivered through SVD, while 21 (24.1%) were born via cesarean section. Similarly, the dry cord care group had 64 neonates (73.6%) born through SVD and 23 (26.4%) via cesarean section. Collectively, 130 neonates (74.7%) in the overall sample were delivered vaginally, and 44 (25.3%) by cesarean section.

Table 1: Gender and Mode of Delivery by Group

Variable	Category	Chlorhexidine Group (n=87)	Dry Cord Care Group (n=87)	Total (n=174)
Gender	Male	42 (48.3%)	40 (46.0%)	82 (47.1%)
	Female	45 (51.7%)	47 (54.0%)	92 (52.9%)
Mode of Delivery	Cesarean Section	21 (24.1%)	23 (26.4%)	44 (25.3%)
	SVD	66 (75.9%)	64 (73.6%)	130 (74.7%)

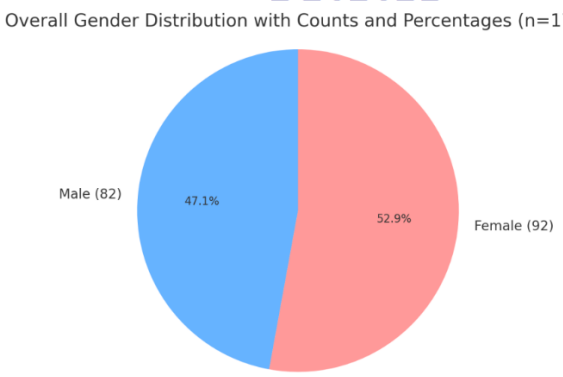

Fig. 1

Comparison of Quantitative Variables

Table 2 summarizes the comparison of key quantitative variables—gestational age, birth weight, and time to umbilical cord separation—between the chlorhexidine group (Group A) and the dry cord care group (Group B), using an independent samples t-test. The mean gestational age was 39.07 ± 1.05 weeks in the chlorhexidine group and 39.21 ± 1.11 weeks in the dry cord care group(p = 0.405), indicating a similar distribution of gestational maturity across the two groups. Similarly, the average birth weight was nearly identical: 3.06 ± 0.31 kg in the chlorhexidine group and 3.05 ± 0.29 kg in the dry cord care group (p = 0.966), suggesting no significant difference in neonatal weight at birth. The mean time in the chlorhexidine group was significantly longer (8.72 ± 3.55 days) compared to the dry cord care group (6.66 ± 2.67 days), with a p-value of <0.001.

Table 2: Assessment of Gestational Age, Birth Weight, and Time to Cord Separation among neonates Receiving Chlorhexidine Versus Dry Cord Care

Variable	Group A (Mean ± SD)	Group B (Mean ± SD)	t-value	p-value[a]
Gestational Age (weeks)	39.07 ± 1.05	39.21 ± 1.11	-0.835	0.405
Birth Weight (Kg)	3.06 ± 0.31	3.05 ± 0.29	0.043	0.966
Time to Cord Separation (days)	8.72 ± 3.55	6.66 ± 2.67	4.318	<0.001

[a] Independent t test

Incidence of Omphalitis Between Study Groups

Table 3 outlines the distribution of omphalitis cases in both the chlorhexidine and dry cord care groups. Among the 87 neonates in the chlorhexidine group, 5 cases (5.7%) of omphalitis were observed, while the remaining 82 neonates (94.3%) did not develop the infection. In the dry cord care group, 3 neonates (3.4%) developed omphalitis and 84 (96.6%) remained infection-free. The overall incidence of omphalitis in the study population was 4.6% (8 out of 174 neonates).(p = 0.469). These findings suggest that both cord care methods are comparable in terms of infection prevention during the neonatal period.

Table 3: Distribution of Omphalitis Cases Between Chlorhexidine and Dry Cord Care Groups

Outcome	Chlorhexidine Group (n=87)	Dry Cord Care Group (n=87)	Total	p-value[a]
Omphalitis - Yes	5 (5.7%)	3 (3.4%)	8 (4.6%)	0.469
Omphalitis - No	82 (94.3%)	84 (96.6%)	166 (95.4%)	

[a]Chi square test

Association Between Gender and Development of Omphalitis

Table 4 examines the relationship between gender and the development of omphalitis across the two intervention groups. Among male neonates, omphalitis was observed in 2 out of 42 (4.8%) in the chlorhexidine group, whereas no cases occurred among the 40 males in the dry cord care group. Among female neonates, 3 out of 45 (6.7%) in the chlorhexidine group and 3 out of 47 (6.4%) in the dry cord care group developed omphalitis. Overall, the incidence of omphalitis was slightly higher among females (6.5%) than males (2.4%). There was no significant correlation between gender and omphalitis incidence, as indicated by p-values of 0.162 for males and 0.956 for females, implying that gender did not affect the likelihood of developing omphalitis.

Table 4: Association Between Gender and Development of Omphalitis

Gender	Chlorhexidine Group (n=87)	Dry Cord Care Group (n=87)	Total	p-value[a]
Male	2 (4.8%)	0 (0.0%)	2 (2.4%)	0.162
Female	3 (6.7%)	3 (6.4%)	6 (6.5%)	0.956
Total	**5 (5.7%)**	**3 (3.4%)**	**8 (4.6%)**	

[a]Chi square test

Mode of Delivery and Its Association with Umbilical Infection Rates

Table 5 evaluates the association between the mode of delivery and the development of omphalitis in neonates within the two study groups. Among those delivered via cesarean section, 3 out of 21 neonates (14.3%) in the chlorhexidine group developed omphalitis, compared to 1 out of 23 (4.3%) in the dry cord care group. In contrast, among neonates delivered through spontaneous vaginal delivery

(SVD), omphalitis occurred in 2 out of 66 cases (3.0%) in the chlorhexidine group and 2 out of 64 cases (3.1%) in the dry care group. Overall, omphalitis was more frequent among cesarean-delivered neonates (9.1%) compared to those delivered via SVD (3.1%). However, the difference was not statistically significant. The Chi-square test yielded p-values of 0.252 for cesarean deliveries and 0.975 for vaginal deliveries, indicating that the mode of delivery did not significantly affect the likelihood of omphalitis in this cohort.

Table 5: Mode of Delivery and Its Association with Umbilical Infection Rates

Mode of Delivery	Chlorhexidine Group (n=87)	Dry Cord Care Group (n=87)	Total	p-value[a]
Cesarean Section	3 (14.3%)	1 (4.3%)	4 (9.1%)	0.252
SVD	2 (3.0%)	2 (3.1%)	4 (3.1%)	0.975
Total	**5 (5.7%)**	**3 (3.4%)**	**8 (4.6%)**	

[a]Chi square test

DISCUSSION:

This randomized controlled trial evaluated the comparative effects of 4% chlorhexidine application versus dry cord care on two critical neonatal outcomes: time to umbilical cord separation (TCS) and the incidence of omphalitis. Conducted in a tertiary care setting in Pakistan, our findings contribute to the ongoing debate regarding the utility and contextual effectiveness of topical antiseptics for umbilical cord care.

In our study, neonates in the chlorhexidine group experienced a significantly longer mean time to cord separation (8.72 ± 3.55 days) than those in the dry cord care group (6.66 ± 2.67 days; $p < 0.001$). These findings are congruent with those reported by Riaz et al. in Pakistan, who observed a TCS of 8.35 ± 3.73 days with chlorhexidine and 6.98 ± 2.59 days with dry care ($p = 0.003$).[11] A similar trend was noted by Wongsurin et al., who reported substantially prolonged separation times in the chlorhexidine group (14.23 ± 4.22 days) compared to alcohol and combined regimens.[12] Likewise, Mullany et al. also reported delayed cord separation with chlorhexidine use.[13]

Conversely, findings from Kapellen et al contradict this trend. In their German study, neonates receiving chlorhexidine powder exhibited a shorter TCS (7.0 ± 2.5 days) than those receiving dry care (7.8 ± 2.9 days; $p = 0.1$).[10] The discrepancy may be attributed to differences in chlorhexidine formulation (powder vs. solution), environmental factors, or variations in hygiene practices. Basnet et al. in Nepal also found negligible differences in TCS between groups (7.77 ± 1.4 days with chlorhexidine vs. 7.70 ± 1.2 days with dry care),[14] while López-Medina et al. reported a mean TCS of 6.61 ± 2.33 days with dry care in Spain.[5] Similarly, Quattrin et al. in Italy demonstrated significantly faster separation with dry care (5.5 ± 1.2 days) compared to alcohol (10.4 ± 2.8 days).[15] Collectively, these findings support the notion that antiseptic use, particularly chlorhexidine, tends to delay cord separation, although the extent of delay may vary across geographical and clinical contexts.

Regarding omphalitis, it was slightly more frequent in the chlorhexidine group (5.7%) compared to the dry care group (3.4%); however, this difference was not statistically significant ($p = 0.469$). These rates are consistent with the findings of Riaz et al., who reported infection rates of 5% and 4% in the chlorhexidine and dry care groups, respectively ($p = 0.73$).[11] Similarly, Kapellen et al. documented 2 cases of omphalitis in the chlorhexidine group compared to 7 in the dry care group, though this difference was not statistically significant ($p = 0.1$).[10]

Nonetheless, several studies have demonstrated a clearer protective effect of chlorhexidine against omphalitis. Kinanu et al. reported that neonates receiving dry cord care had nearly twice the risk of omphalitis compared to those receiving chlorhexidine (AOR = 1.95; 95% CI: 1.13–3.38).[16] Dhingra et al. found a 35% reduction in omphalitis risk with chlorhexidine use (RR = 0.65; 95% CI: 0.61–0.70).[17] In addition, Prabha et al. and Muhammad Ishaq et al. both reported significantly lower rates of umbilical infections with

chlorhexidine application, supporting its role in sepsis prevention, particularly in resource-limited settings.[18-19]

Broader public health data also support chlorhexidine's utility. Singh et al. highlighted low chlorhexidine coverage rates of 15.0% in Bangladesh and 50.7% in Nepal, with significantly greater use associated with facility-based deliveries.[20] These findings underscore the potential impact of scaling up chlorhexidine use in rural and underserved areas to reduce neonatal infections.

Contrasting evidence from high-resource settings suggests that dry care may be equally effective when hygienic conditions are ensured. Gras-Le Guen et al concluded that dry care offers comparable safety and faster cord separation in such environments.[21] Another study demonstrated significantly shorter TCS with dry care compared to alcohol (7 ± 1 vs. 16 ± 1 days; $p = 0.021$), with no omphalitis reported in either group.[22] Wang et al. further emphasized the role of caregiver education, showing that an "Internet Plus" intervention significantly reduced cord infections (2.8% vs. 14.3%; $p = 0.027$).[23]

We also explored demographic factors associated with omphalitis. While female neonates had a slightly higher infection rate (6.5%) than males (2.4%), the difference was not statistically significant ($p = 0.956$). This finding aligns with most existing literature, which does not identify gender as a consistent risk factor.[5,24] Similarly, while cesarean-delivered neonates showed a trend toward higher infection rates (9.1% vs. 3.1% in vaginal deliveries), the difference was not significant ($p = 0.252$), though it merits further investigation considering potential delays in postnatal care and altered microbial exposure.

Educational status of mothers emerged as a potentially influential factor. A Turkish randomized trial found significantly shorter TCS in neonates whose mothers received prenatal cord care education (6.60 ± 0.18 days vs. 10.97 ± 0.32 days; $p < 0.05$).[25] These findings underscore the value of maternal health literacy in optimizing neonatal outcomes.

In summary, our study aligns with global evidence indicating that while chlorhexidine use delays cord separation, its impact on omphalitis prevention may be context-specific. In settings with high infection risk and limited hygiene, chlorhexidine may confer measurable benefits. However, in adequately sanitized hospital environments such as ours, dry cord care remains a safe, effective, and cost-efficient alternative, offering significantly faster cord separation without an associated increase in infection risk.

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