

Comparison of the Impact of Topical Chlorhexidine Versus Methylated Spirion Umbilical Cord Sloughing Time in Neonates

Irshad Hussain, Sughra Wahid, Maliha Akhtar Qureshi, Fasih ul Islam Hashmi*, Muhammad Fahim

KRL Hospital, Islamabad Pakistan, *Allamah Iqbal Open University Islamabad Pakistan

ABSTRACT

Objectives: To study the impact of applying topical Chlorhexidine compared with Methylated spirit on umbilical cord sloughing time in neonates.

Study Design: Quasi-experimental study.

Place and Duration of Study: Paediatric Department, KRL Hospital, Islamabad Pakistan from Oct 2018 to Mar 2019.

Methodology: A total of 100 neonates were enrolled in each Group, i.e., Chlorhexidine and Methylated spirit. After taking informed consent from the parents, the treatment was applied twice daily for five days. Parents had telephonic interviews about the signs of umbilical cord infection on day two following enrollment in the study, and then babies were examined for signs of omphalitis during each hospital visit on days-7, 14 and 21. Umbilical cord sloughing time was noted.

Results: Both Groups were independent (statistically insignificant) with respect to neonatal birth weight, gestational age, neonatal sex, mode of delivery and type of feed with *p*-values of 0.258 and 0.17, 0.066, 0.304 and 0.143, respectively. The result showed that the mean rank of cord sloughing time with the Methylated spirit was significantly less than Chlorhexidine, with the *p*-value of 0.001.

Conclusion: Based on our results, we concluded that the application of Methylated spirit on the umbilical cord shortens the sloughing time compared to Chlorhexidine, but both treatments have comparable efficacy in preventing omphalitis.

Keywords: Chlorhexidine, Methylated spirit, Neonatal sepsis, Omphalitis, Umbilical cord care, Umbilical cord sloughing time.

How to Cite This Article: Hussain I, Wahid S, Qureshi MA, Hashmi FUI, Fahim M. Comparison of the Impact of Topical Chlorhexidine Versus Methylated Spirion Umbilical Cord Sloughing Time in Neonates. *Pak Armed Forces Med J* 2022; 72(4): 1392-1396.

DOI: <https://doi.org/10.51253/pafmj.v72i4.6542>

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INTRODUCTION

In developing countries, sepsis is one of the major causes of neonatal mortality, and the umbilical cord plays a significant role in being a main conduit of infection.¹ Umbilical cord sloughs off usually within the first 14 days of neonatal life.² Delayed UCS can increase the risk of omphalitis and neonatal infections, especially beyond four weeks after birth. Eventually, chances of neonatal mortality are increased.² Therefore, umbilical cord care is of considerable importance. However, the ideal and the most effective practices for postnatal cord care among health care professionals are still debated. Umbilical cord cleansing and care are performed through different antiseptics, including alcohol, Methylated spirit, Chlorhexidine (CHX), tincture of iodine, bacitracin, neomycin, silver sulphadiazine, gentian violet and even human milk.³

CHX is a commonly used topical antiseptic agent that acts against aerobic and anaerobic bacteria, reduces bacterial colonization, and may also reduce neonatal infection.⁴ A systemic review in 2019 found that applying topical CHX for cord care in developing

countries reduces severe sepsis by 77% and neonatal mortality by 13% versus dry cord care.⁵ It also decreases the incidence of omphalitis in community and/or low resource settings.^{5,6} However, its impact on UCS time shortening is still controversial. Studies by Kapellen *et al.* and Shwe *et al.* show that topical CHX is associated with shorter UCS time compared to dry cord care and Methylated spirit, respectively.^{7,8}

Nevertheless, studies done by other researchers show that its use prolongs UCS time.^{4,9} 4% Ethyl Alcohol, commonly identified as Methylated spirit, is used as a topical antiseptic for cord care.³ Its efficacy is comparable to CHX in terms of the prevention of omphalitis.⁸

It is needful to mention that mothers in Pakistan are often worried and anxious about the time it takes for the cord to slough off. As a result, mothers carry out different unscientific practices to shorten the UCS time, such as the use of toothpaste, ghee, mustard oil, coconut oil, petroleum jelly, clove oil, Surma (locally made kohl), turmeric, Dettol liquid, cold cream and hot compress with sand, without knowing that such practices can predispose the child to the risk of neonatal tetanus and neonatal sepsis.¹⁰ Methylated spirit is also commonly used for umbilical cord care in

Correspondence: Dr Irshad Hussain, Department of Pediatric, KRL Hospital, Islamabad, Pakistan

Received: 06 Apr 2021; revision received: 29 Apr 2021; accepted: 04 May 2021

Pakistan. However, as per our knowledge, no study in Pakistan has been conducted to identify the impact of Methylated spirit on UCS time and its comparison with topical CHX. The present study investigates the impact of topical CHX compared with Methylated spirit on UCS time in neonates and compares their efficacies in preventing omphalitis.

METHODOLOGY

This quasi-experimental study was conducted at KRL Hospital Islamabad, a tertiary care hospital recognized by the College of Physicians and Surgeons Pakistan for post-graduate training in many fields, including paediatrics. Study was conducted from Oct 2018 to Mar 2019.

The sample size was calculated through the World Health Organization (WHO) calculator from the study conducted by Shwe *et al.*⁸ who examined the efficacies of Methylated spirit and CHX on cord separation time and found that mean cord separation was 7.96 ± 4.07 days in Methylated spirit Group vs 6.43 ± 3.13 days in CHX Group. Keeping the power of the test at 80% and the significance level at 95%, the minimum sample size to compare the two Groups was 87 in each Group. Thus, we included 100 patients in each Group.

Inclusion Criteria: Apparently healthy babies, of gestational age ≥ 37 weeks, 1 and 5 minutes APGAR score of $>7/10$, weight ≥ 2.5 kg, not receiving antibiotics or anti-inflammatory drugs, and mothers receiving tetanus toxoid vaccination were included in the study.

Exclusion Criteria: Neonates excluded were those born premature, having birth asphyxia, congenital anomalies, respiratory distress, any other problem requiring immediate admission to the neonatal intensive care unit, or maternal history of prolonged membrane rupture >18 hours at birth.

Data was collected after approval by the Ethical Review Committee of the hospital (Approval Certificate No. ERC-18/09/01). Detailed clinical history and thorough physical examination of the newborns were carried out prior to enrollment. A total of 100 newborns were enrolled in each Group who met the inclusion criteria through consecutive sampling. Neonates were alternatively allocated in Methylated spirit and CHX Groups.

Accordingly, in the first week of the study, all newborns who met the inclusion criteria were allocated to the Methylated spirit Group, while in the second week, all the neonates were allocated to the

CHX Group. Therefore, the mothers of one Group do not communicate with the other Group. This weekly alternation process was repeated until 100 neonates were recruited to each Group. Informed consent was taken from the parents, including their willingness for follow-up visits and telephonic interviews.

A training session was conducted with the mother, father and an accompanied caregiver three hours after the birth of the baby about the importance of umbilical cord care, signs of infections and the method to apply the agents on the umbilical stump and on the skin surrounding the base of the stump using a cotton swab. The baby received the first dose of either CHX gel or Methylated spirit in the presence of the researcher, and then they were asked to repeat the application twice daily for five days. They were provided with adequate test agents for their home use and were asked to bring the baby immediately if redness appeared at the umbilicus. Otherwise, they were told to visit the hospital on days 7, 14 and 21. Parents were interviewed on the phone on day two following enrollment into the study.

They were asked about their compliance and any signs of infection like redness and/or swelling around the cord stump and pus discharge. Then, during their every visit to the hospital on the mentioned days, the babies were evaluated for signs of omphalitis (oozing of foul smelling discharge from the stump along with the peri umbilical redness and swelling); otherwise, the efficacy of the user agent and sloughing time were noted. The primary outcome measure was UCS time, whereas the secondary outcomes were the signs of infection and the development of omphalitis.

Statistical Package for Social Sciences (SPSS) version 23.0 was used for the data analysis. Descriptive stats were calculated for both qualitative and quantitative variables. Quantitative variables like Gestational age in weeks, neonatal weight and UCS time in days were presented as mean and standard deviation. Qualitative variables like neonatal sex, mode of delivery, type of feed, neonatal sepsis, discharge of pus, redness and omphalitis were presented in frequency and percentages.

Mann Whitney U test was used to compare the median cord sloughing time between the two Groups. Chi-square test was used to compare the risk factors, i.e. neonatal sex and mode of delivery and complications, i.e., discharge of pus, redness and omphalitis. The *p*-value less or equal to 0.05 was considered significant.

RESULTS

The average gestational age of 200 subjects was 37.95±0.77 weeks. There were 105 (52.5%) males and 95 (47.5%) females in 200 neonates with an average weight of 3.05±0.35 kg with a minimum and a maximum weight of 2.5 kg and 4.2 kg, respectively. The majority of 127 (63.5%) births were through Lower Segment Cesarean Section (LSCS), while 73 (36.5%) births were through Spontaneous Vaginal Delivery (SVD). The majority of the neonates were on exclusive breastfeeding 21 (60.5%), 57 (28.5%) were on both breastfeeding and bottle feed, and the remaining 22 (11%) were on bottle feed only. The distribution of subjects regarding neonatal sex, mode of delivery and type of feed in the two Groups, i.e., CHX or Methylated spirit, were mentioned in Table-I. Both treatment Groups were independent (statistically insignificant) with respect to gestational age and neonatal weight, with *p*-values of 0.17 and 0.258, respectively (Table-II).

not normality distributed in both Groups, i.e., CHX and Methylated spirit, with *p*-values of 0.007 and <0.001.

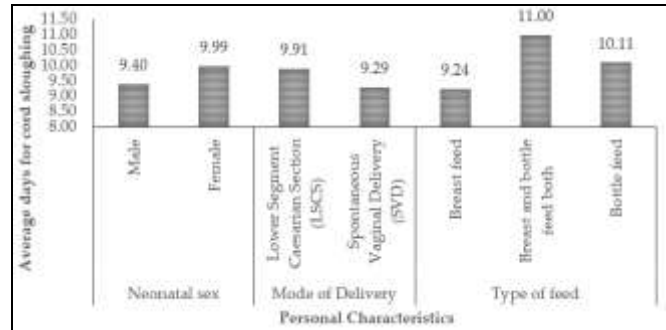


Figure: Comparison of average Umbilical Cord Sloughing time in days with respect of different personal characteristics (n=200)

Wilcoxon signed rank test showed that the median UCS time with CHX was at least nine days

Table-I: Distribution of Qualitative Characteristics between two groups (n=200)

Variables	Categories	Chlorhexidine n=100	Methylated spirit n=100	<i>p</i> -value
Neonatal Sex	Male	46	59	0.066
	Female	54	41	
Mode of Delivery	Lower Segment Cesarean Section (LSCS)	67	60	0.304
	Spontaneous Vaginal Delivery (SVD)	33	40	
Type of feed	Breastfeed	54	67	0.143
	Breast and bottle feed both	32	25	
	Bottle feed	14	8	

Table-II: Distribution of Quantitative Characteristics between two Groups (n=200)

Variables	Groups	Minimum	Maximum	Mean±Standard Deviation	<i>p</i> -value
Gestational age(weeks)	Chlorhexidine	37	40	37.88±0.76	0.17
	Methylated spirit	37	40	38.03±0.78	
Neonate weight(kg)	Chlorhexidine	2.5	4.2	3.02±0.36	0.258
	Methylated spirit	2.5	3.7	3.08±0.33	

The average UCS time in neonates on exclusive breastfeeding was shorter than those who were also taking bottle feed along with breastfeeding or were on bottle feed only (Figure).

The mode of the UCS time in the patients treated with CHX was ten days, having a minimum of 4 days and a maximum of 20 days with semi interquartile range or quartile deviation was found to 2.38; whereas in the second Group where patients treated with Methylated spirit the mode of UCS time was found seven days having minimum three days and maximum 25 days with semi interquartile range 2.88. As the UCS time was a quantitative variable, we first tested the normality of the variable in both Groups. Then, the Shapiro-Wilk test was used to test the normality of the variable. The normality test showed that UCS time was

with a *p*-value <0.001. The median UCS time with Methylated spirit was at least seven days with a *p*-value of <0.001. The Mann-Whitney U test was used to compare the mean rank of cord sloughing time between CHX 114.27 and Methylated 86.73 with a *p*-value of 0.001.

Both treatment Groups were equally efficient in preventing umbilical cord complications, as in Table-III. All complications, i.e. neonatal sepsis, pus discharge, redness and omphalitis, were not associated with any specific treatment Group with *p*-values 0.651, 0.241, 0.096 and 1.000, respectively.

DISCUSSION

Based on the results of our study, the average UCS time obtained with the Methylated spirit was shorter (7 days) compared to CHX (10 days), which is

similar to the recent findings of other researchers. For example, in a study conducted in 2019, the researchers reported that the average cord separation time in the Methylated spirit Group was shorter, 7.98 days, compared to 9.53 days with the CHX Group.¹¹ Similarly, in another study, the researchers compared CHX with dry cord care and showed a statistically significant difference in the average cord separation time of 13.28 with CHX and 7.85 with dry cord care, with a *p*-value of 0.0014. Similar results were also reported by other researchers from Bangladesh.^{12,13}

Table-III: Comparison of treatment groups with respect of complications (n=200)

Complications		Chlorhexidine Group n=100	Methylated Spirit Group n=100	<i>p</i> -value
Neonatal Sepsis	Yes	2	3	0.651
	No	98	97	
Pus Discharge	Yes	5	2	0.241
	No	95	98	
Redness	Yes	10	4	0.096
	No	90	96	
Omphalitis	Yes	2	2	1.000
	No	98	98	

In another study, CHX was compared with the dry cord method, and it was found that the average cord separation time CHX Group was longer as compared to the other Group.¹³ The results of two more systematic meta-analyses are also in the same direction.^{5,14}

In a study conducted in Nepal and Bangladesh, the researcher included 3223 newborn babies. The results showed that average cord separation was longer in the CHX Group (6.5 days) compared to non-CHX Groups (5.1 days). They also found that the relative mortality risk in CHX compared to non-CHX was 0.54. In addition, the risk of mild and moderate omphalitis was lower with CHX, with a relative risk of 0.6 and 0.54, respectively.^{15,16}

In another randomized open-labelled parallel-Group trial, the average cord separation time with the Methylated spirit was observed at 7.96 days and that of CHX at 6.43 days. The researchers concluded that both the agents are equally efficient in UCS time and prevention of omphalitis with a *p*-value of 0.078 and can be used as a safe alternative to each other.⁸

Some researchers observed a short cord separation time with the application of CHX. A study conducted in 2012 shows that the average UCS time with the CHX Group (6.22 days) was significantly shorter than 70% alcohol Group (7.10 days),¹⁶ which is

contrary to our present study. While researchers in Southern Nepal,¹⁷ observed the average cord separation time of 5.32 days with CHX and 7.49 days in a study conducted in Bangladesh,¹⁸ both of these studies show shorter cord separation time with CHX compared to ours.

Although UCS time was increased in the CHX Group compared to the Methylated spirit Group in our study, cases of omphalitis observed in each Group were equal and insignificant, i.e., only 2 cases in each Group, which means that both treatment methods have similar efficacy in terms of prevention of omphalitis. This is comparable to the study conducted in Turkey in which it was found that CHX application prolongs UCS time, but only one case of omphalitis was observed in this Group.¹⁹

The findings of our study also showed that the UCS time is not affected by mode of delivery which is contrary to other studies^{7,20} which show that UCS time is shorter in neonates delivered vaginally, while neonates born via caesarean section have a longer UCS time.

Delayed UCS can increase the risk of infection² Therefore, cord care is of great importance. A Systematic review of 65 articles from January 2000 to August 2016 was planned in 2017. The selected articles were from 15 low and middle-income countries. The researchers concluded that the documentation of cord care practice is inconsistent throughout low- and middle-income countries. The diversity in cord care practice is due to area (rural/urban), mode of delivery, neonatal weight, neonatal birth site (hospital/home) and culture.²¹ That is why the cord care practice should be examined in different countries, cultural Groups and casts. For example, in Pakistan, the cord care practices should be examined in rural and urban areas of each province, including the capital.

CONCLUSION

Based on our results, we concluded that UCS time is shorter in the Methylated spirit Group compared to the CHX Group, but both treatments have comparable efficacy in the prevention of omphalitis. It is also a well-known fact that Methylated spirit is easily available and cost-effective so that it can be used safely for early cord sloughing and the prevention of omphalitis. The study results strengthen the fact.

Conflict of Interest: None.

Author Contribution

IH: Data collection, writing of the manuscript, corresponding author, SW: Study conception, design and supervision,

MAQ: Supported institutional ethical approval process and data collection, FUIH: Data analysis and interpretation, MF: Critical revision of the article.

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