

## A Cross Sectional Comparative Study of Methylated Spirit and Chlorhexidine in Preventing Neonatal Cord Infections in a Local Hospital, Jos- Plateau State, Nigeria

Chukwuebuka Francis Okoye<sup>1</sup>, Emeka Emmanuel Okoh<sup>2</sup>, Terna Ager<sup>1</sup>, Osita John Ikpeama<sup>3</sup>, Ikechukwu Joseph Ogbodo<sup>1</sup>, Ivan Aguyi<sup>1</sup>, Oluebube Aphonsus Okoye<sup>4</sup>, Jerisha Kakwi<sup>5</sup>, Kosisochukwu Udeogu<sup>6</sup>, Chiagozie Ozoemena ifeadike<sup>2</sup> and Preye Agadagidi Kingsley<sup>1</sup>

<sup>1</sup>Nigerian Air force Military Hospital, Jos. <sup>2</sup>Department of Community Medicine and Primary Health Care, Nnamdi Azikiwe University, Awka. <sup>3</sup> 8 Division Medical Services and Hospital, Sokoto. <sup>4</sup> Faculty of Pharmaceutical Sciences, Nnamdi Azikiwe University, Awka. <sup>5</sup> Plateau State Primary Health Care Development Agency. <sup>6</sup> University of Nigeria Teaching Hospital, Nsukka.

### ABSTRACT

**Background:** The care of the umbilical cord is very vital during the early postnatal period. This is because it could constitute a source of infection if left unkempt leading to neonatal morbidity and mortality. **Objectives:** This study aims to determine if Chlorhexidine is more efficacious than the methylated spirit in preventing Omphalitis, Neonatal sepsis and Neonatal mortality. **Materials and Methods:** This was a cross sectional comparative study of methylated versus chlorhexidine gel with 20 and 14 mother-baby pairs, respectively, conducted in 563 Nigerian Air Force Military (NAF) Hospital, Jos, between the 1<sup>st</sup> to 30<sup>th</sup> September 2021. SPSS version 23 was used for data analysis to examine for incidence of omphalitis, time-to-cord separation, NNS and mortality. **Results:** Most of the women who participated in the study were between 30 to 36 years. Both agents gave similar outcomes within the first four days of life. In both groups, cord separation was mostly on days 7–9. The median (IQR) separation time was 8 (7 – 9.25) and 8 (7 - 13) for chlorhexidine and methylated spirit group respectively. An independent sample t-test for non-normally distributed data – Mann-Whitney U test, was conducted to assess any difference in the mean separation time of both groups. With a P-value at 0.05, the results showed that there was no statistically significant difference in the separation time of both groups. Therefore, any difference between both groups was due to chance. **Conclusion:** Chlorhexidine is not superior to Methylated spirit in preventing Omphalitis, neonatal sepsis, and neonatal infections in resource-constrained environments. It is therefore important that the use of methylated spirit should be encouraged, especially when caregivers cannot afford Chlorhexidine.

**Keywords:** Chlorhexidine; Methylated spirit; Neonatal infection; Neonatal sepsis; Omphalitis

### INTRODUCTION

After delivery, the choice of an effective antiseptic product to care for the Umbilical cord is considered very important to reduce the risk of

#### OPEN ACCESS

#### \*Correspondence:

CF Okoye. Cardiovascular Research Unit, University of Abuja/University of Abuja Teaching Hospital.

#### Email:

[Chukwuebukafrancisokoye@yahoo.com](mailto:Chukwuebukafrancisokoye@yahoo.com)

#### Specialty Section:

This article was submitted to Medicine, a section of TJMR

Received: 13 August 2022

Accepted: 4 December 2022

Published: 15 December 2022

#### Citation:

CF Okoye, EE Okoh, T Ager, OJ Ikpeama, IJ Ogbodo, I Aguyi. A Cross Sectional Comparative Study of Methylated Spirit and Chlorhexidine in Preventing Neonatal Cord Infections in a Local Hospital, Jos- Plateau State, Nigeria. Trop J Med Res. 2022;21(2);85-92. DOI: 10.5281/zenodo.7792906

#### Access Code



<http://tjmr.org.ng>

developing complications as a result of poor care. Cord care is the series of steps applied in the handling of the umbilical cord after delivery of the newborn, which if not meticulously carried out will significantly contribute to newborns' risk of infection and mortality.[1-3] Globally, about 130 million babies are delivered annually with an estimated 4 million deaths occurring within the first 4 weeks of life, and about 1.5 million [30 per cent] deaths are attributable to infections.[4,5-7] Several studies have been conducted to document different cord care practices [8], where some of these are beneficial others are not. In a rural community in Pakistan, a study done on topical application of chlorhexidine to the neonatal umbilical cord for the prevention of Omphalitis and neonatal mortality showed strong evidence of a reduction in neonatal mortality in neonates who received Chlorhexidine (CHX) cleansing.[9] In addition, systematic reviews and meta-analysis done in Nepal, Bangladesh and Pakistan on the effect of umbilical cord cleansing with Chlorhexidine on omphalitis and neonatal mortality in community settings in developing countries reported that the application of CHX to the umbilical cord of newborns led to a reduction in all causes of Neonatal mortality including Umbilical cord infection.[10] Studies conducted in Cameroon and Nigeria both in the West African sub-region reported unsatisfactory levels of cord care practices among mothers, resulting in an increased risk of infections and mortality in the neonatal period.[11,12] In Nigeria, several hospital-based studies have reported cases of umbilical cord infections accounting for between 10 and 19% of neonatal admissions leading to as much as 30–49% of neonatal deaths [13] Based on this, World Health Organization advocates for dry umbilical cord care, and the use of topical antiseptics in situations where hygienic conditions are poor or infection rates are high.[3,14] However, the Nigerian Ministry of Health recommends the use of Methylated spirit or chlorhexidine solution for cord care.[4,15] The Nigerian government recommends the use of methylated spirit for cord care [16,17], which conforms with the World Health

Organization's advocacy for the use of topical antiseptics in umbilical care in situations where hygienic conditions are poor or infection rates are high. [18,19] And several studies done have confirmed the use of Chlorhexidine solution as an effective alternative for the methylated spirit. Despite these recommendations by the Nigerian Government on cord care and acclaimed practice report from some of these mothers, we still have recorded cases of umbilical cord infections especially with mothers who applied Chlorhexidine gel.[20] However, a study done in Jos north-central Nigeria earlier this year reported that both Chlorhexidine and Methylated spirit are safe and effective alternatives for umbilical cord care.[12] While most hospital in the southern part of Jos focus on the use of chlorhexidine as the best option, this study aims to determine if Chlorhexidine is more efficacious than the methylated spirit in preventing Omphalitis, Neonatal sepsis and Neonatal mortality in Jos south.

## MATERIALS AND METHODS

### Study design, site and date:

This was a pilot open-labelled study, parallel-group comparison of Methylated Spirit (MOKO) and topical 4% CHX gel in prevention of omphalitis.

It was conducted in the Nigeria Air Force Military Hospital's Maternity department situated at Plot 330, Rayfield Road, NAF Station, Old Airport Road, Jos, Plateau State, Nigeria. The health facility is a 50-bed capacity secondary level Healthcare facility with an average of 50 deliveries per month. The study was conducted between the 1<sup>st</sup> and 30<sup>th</sup> September, 2021.

**Study population:** It comprised newborns in the maternity ward of 563 Nigerian Airforce military Hospital in Jos, Plateau state, Jos South.

**Sample size estimation:** 10% of the required sample population was used to pilot the study.

**Inclusion criteria:** The Inclusion criteria for this study were apparently healthy term hospital greater

or equal to 0 to less than or equal to 6 hours with written informed consent of parents or legally acceptable representative (LAR) and their willingness for return visits to the delivery hospital or Telephone interview per study protocol while structural birth defects where the topical application of test agents is impossible (Omphalocele, Gastroschisis), clinical or laboratory evidence of Sepsis, Maternal Peripartum Pyrexia, prolonged rupture of fetal membranes or evidence of Chorioamnionitis, Human immunodeficiency virus/Hepatitis B virus/ Hepatitis C Virus seropositive mothers and hypersensitivity to any of the topical test agents were excluded

**Selection of enrollees:** Eligible enrollees were allocated to one of the treatment groups.

**Subject of selection, screening and recruitment:**

Subjects were identified, screened and carefully enrolled into groups. Prior to enrollment, full clinical history was obtained and a thorough physical examination was carried out. Relevant medical information obtained (age, sex, gestational and mode of delivery, risk for sepsis, history of sensitivity to test agent, maternal age, parity, vaccination status, weight, temperature, structural defect) were documented on case report forms (CRF). Caregivers were taught in addition to the clinical demonstration, the procedure for topical application of test agents and proper hand-washing technique.

**Treatment allocation procedure:** Four per cent topical CHX gel was applied generously on the umbilical stump and spread around the abdominal wall area that comes into contact with the stump using the index finger. This was carried out twice daily and at any other of the day, the stump appeared wet and when the baby is about to be breastfed. On the other hand, a clean piece of cotton wool soaked in dispensed 50mls container of 99.97% methylated spirit (MOKO) was used in the cleaning of the stump and the cord clamp every two hours. The cleansing procedure started from the tip of the

stump towards the cord clamp and proximally to the base of the stump. Caregivers were also provided with more test agents whenever they were exhausted. Eligible enrollees were allocated to one of the treatment groups. Caregivers had telephone interviews on day 2 following enrolment into the study. Information of interest on the checklist were: fever, redness around cord stump, bleeding, bad odour or purulent discharge, swelling, frequency of cord care, cord separation time, evidence of Omphalitis and or sepsis. Questions were solicited for the use of other agents out of study protocol. Furthermore, enrollees had telephone interviews on days 7, 14, 21 and 28 or any other days within study protocol when there are study-related concerns. In the event of diagnosis of probable sepsis, based on WHO Guidelines for Omphalitis (erythema, foul-smelling discharge around the cord), the patient was hospitalized in the Air Force Hospital. Blood culture and cord swab were carried out. The affected neonates received our hospital's standard of care for Neonatal sepsis therapy.

**Intervention**

**Test agents:** Topical Chlorhexidine digluconate 7.1% (equivalent to 4% chlorhexidine gel): 4% CHX (25g of 4% Chlorxy-G Gel, Batch N0 CGH2, manufactured date: 03/20 and expiry date: 02/23) for application on cord stump according to manufacturer's instructions and Topical 99.97% methylated spirit (MOKO) were provided.

**Demonstration on topical applications of the test agents:**

Demonstration session for mothers were carried out by the investigator. They were conducted one-on one basis.

**Administration of treatment agents:** Four per cent topical CHX gel was applied generously on the umbilical stump and spread around the abdominal wall area that comes into contact with the stump using the index finger. This was carried out twice daily and at any other of the day, the stump appeared wet. On the other hand, a clean n piece of cotton wool soaked in dispensed 50mls container of

99.97% methylated spirit (MOKO) was used in the cleaning of the stump and the cord clamp every two hours. The cleansing procedure started from the tip of the stump towards the cord clamp and proximally to the base of the stump.

**Data collection tool:** CRF was used to document clinical information. It had three sections: Section A- Biodata and obstetric information of mother, Section B – Biodata, perinatal health information, temperature and anthropometry measurements of the newborns and Section C- comprised clinical follow-up visits of the enrollees from day 7, day 14, day 21 and day 28 including NNS and omphalitis symptoms checklist.

#### Definition of key terms of the study

*Cord separation time:* This is defined as the time

(days) taken for the umbilical cord to dry and completely fall off from the cord stump. Solicited adverse reactions such as dermatitis, anaphylaxis will be recorded on Case Report Forms (CRF).<sup>7,13</sup> Any study subject who developed such reactions were given alternative treatment.

*Protocol violation:* A study subject was judged to have violated protocol if there is evidence to suggest any of the following: Use or application of a different treatment agent outside study protocol, the umbilical stump was cut manually for any reason and or did not apply treatment agent according to protocol.

#### Outcome measures

The primary outcomes were the development of Omphalitis, Neonatal Sepsis and the occurrence of mortality until Day 28. The secondary outcome measure was also cord separation time (days). Adverse reactions to test agents were documented.

## RESULTS

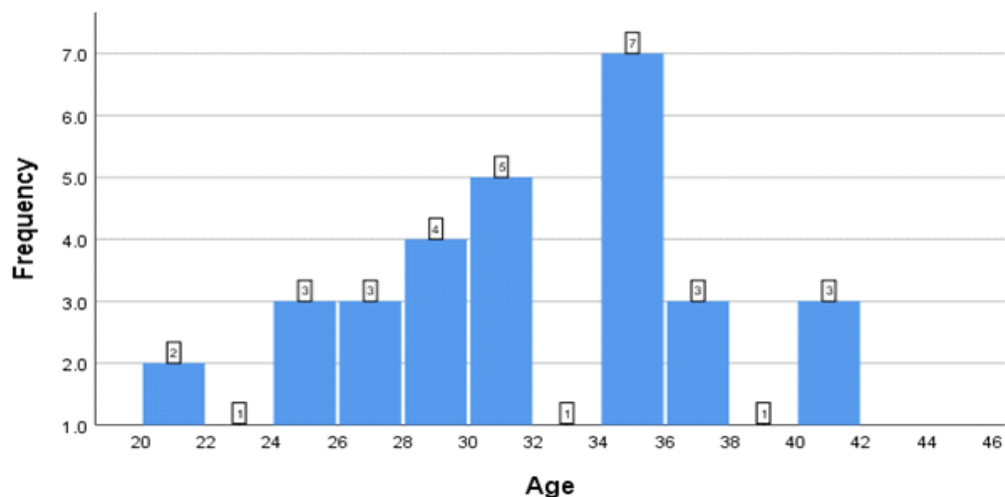


Figure 1 shows the age distribution of mothers. They were mostly within the ages of 30 – 36yrs.

**Table 1: Comparing the Effectiveness of Chlorhexidine and methylated Spirit in Preventing Umbilical Cord Infection**

	Day 7	Day 14	Day 21	Day 28
<b>CHLORHEXIDINE</b>				
Fever	Nil	Nil	Nil	Nil
Redness	Nil	Nil	Nil	Nil
Bleeding	Nil	Nil	Nil	Nil
Odour	Nil	Nil	Nil	Nil
Discharge	Nil	Nil	Nil	Nil
Swelling	Nil	Nil	Nil	Nil
<b>METHYLATED SPIRIT</b>				
Fever	Nil	Nil	Nil	Nil
Redness	Nil	Nil	Nil	Nil
Bleeding	Nil	Nil	Nil	Nil
Odour	Nil	Nil	Nil	Nil
Discharge	Nil	Nil	Nil	Nil
Swelling	Nil	Nil	Nil	Nil

Table 1: show the effectiveness of chlorhexidine and methylated spirit up to day 28 of life. The tables show that both chlorhexidine and methylated spirit gave the same outcome amongst participants.

**Table 2: Comparing 2 Separation Time (In Days) Between Participants Who Used Chlorhexidine and Methylated Spirit**

	AGENT		T <sub>1</sub>	P-Value
	CHLORHEXIDINE E (%)	METHYLATED SPIRIT (%)		
Separation time (days)			1 <sup>a</sup>	0.604
0 – 3	1 (7.1)	1 (5.3)		
4 – 6	2 (14.3)	1 (5.3)		
7 – 9	9 (64.3)	10 (52.6)		
10 – 12	1 (7.1)	2 (10.5)		
13 – 15	1 (7.1)	5 (26.3)		
<b>Total</b>	14 (100.0)	19 (100.0)		
<b>Mean (SD)</b>	8.57 (3.0)	9.21 (3.2)		
<b>Median (IQR)</b>	8 (7 – 9.25)	8 (7 - 13)		

<sup>a</sup> Mann-Whitney U test, SD = Standard Deviation, IQR = Inter-quartile range

Table 2 compared the separation time of the 'navel' amongst participants who used chlorhexidine and methylated spirit. In both groups, separation was mostly on days 7 – 9. The median (IQR) separation time was 8 (7 – 9.25) and 8 (7 - 13) for chlorhexidine and methylated spirit group respectively. An independent sample t-test for non-normally distributed data – Mann-Whitney U test, was conducted to assess any difference in the mean separation time of both groups. With a P-value set at 0.05, the results showed that there was no statistically significant difference in the separation time of both groups. Therefore, any difference in the separation time between both groups was due to chance. There was no protocol deviation.

## DISCUSSION

Within the limitations of a small-sized database, the study shows that both chlorhexidine and methylated spirit gave the same outcome amongst participants in the prevention of umbilical cord infection. This finding aligns with the study done by Mullany et al [21], which showed that the use of 4.0 per cent Chlorhexidine (CHX) for topical cord antiseptics represents an important intervention with the potential for substantial effect on public health. Thus, this strong safety record, low cost and ease of implementation make cord cleaning with 4.0 per cent CHX an ideal intervention, even for mothers, traditional birth attendants or other people with little training who might assist with deliveries in low resource settings. However, this contradicts a study done by Shwe et al [22] which reported that there were more cases of Omphalitis in the CHX compared to the methylated spirit treatment group, which may be due to the method of cord care by respective mothers.

The mean cord separation time in the Methylated spirit treatment group was mostly the same when compared to the CHX gel treatment group. The difference was not statistically significant. Therefore, any difference in the separation time between both groups was due to chance which is similar to a study done by Shwe et al [22], that shows that though the methylated spirit treatment group was longer compared to the CHX gel treatment group. The difference was not statistically significant. Finally, in resource-poor sub-Saharan African, Chlorhexidine is not readily available to mothers because of the cost implications and its scarcity in most pharmacies and patent drug stores. It is easily accessible in Government facilities, through funding and aids from the WHO and other international organizations. However, this is not the case for the methylated spirit which is readily available in remote drug stores because of the other benefits it accrues in asepsis.

The discussion needs to be more robust, to delve more on the implications of the findings of this study on what is already known (or unknown) about

the subject matter.

## CONCLUSION

Chlorhexidine is not superior to Methylated spirit in preventing Omphalitis, neonatal sepsis and neonatal infections in a resource-constrained environment. It is therefore important that the use of methylated spirit should be encouraged, especially when caregivers cannot afford Chlorhexidine.

## Acknowledgement

We sincerely appreciate the patients who participated in the research and the entire nurses of the Maternity department of the 563 Nigerian Air Force Military (NAF) Hospital, Jos. I appreciate Dr Shew David, Dr Pannan and Dr Faya shalom for their support and help during this work.

## Author contributions:

CFO conceptualize the idea, drafted the study design and administered the questionnaire, EEO and OJI edited the manuscript, KU analyzed the data and all others edited and worked on the manuscript

## Data availability

The data used to support the findings of this study are available from the corresponding author upon reasonable request.

**Funding:** No funding sources

**Conflicts of Interest:** None declared

**Ethical approval:** The study was approved by the Nigerian Air Force's Ethics Committee.

## REFERENCE

1. World Health Organization (WHO). Care of the Umbilical Cord: A Review of the Evidence. (1998). Available from: <http://bvssper.paho.org>
2. Zupan J, Garner P, Omari AAA. Topical umbilical cord care at birth. *Cochrane Database Syst Rev* (2004) (3):CD001057. doi:10.1002/146518.CD001057.pub2
3. Bhatt B, Malik JS, Jindal H, Sahoo S, Sangwan



- K. A study to assess cord care practices among mothers of newborns urban areas of Rohtak Haryana. *Int J Basic Appl Med Sci* (2015) 5(1):55–60.
4. Osuorah DIC, Ekwochi U, Onah S, Bernard EE. Umbilical cord care practices and incidence of febrile illnesses in the first month of life among newborns—a population-based study. *Br J Med Med Res* (2015) 5(11):1422–30. doi:10.9734/BJMMR/2015/14056
  5. Osuchukwu EC, Ezeruigbo CSF, Eko JE. Knowledge of standard umbilical cord management among mothers in Calabar South local government area, cross river state, Nigeria. *Int J Nurs Sci* (2017) 7(3):57–62. doi:10.5923/j.nursing.20170703.01
  6. Peter O, Johnson J. Risk factors for neonatal infections. *Global J* (2010) 12:40–6. [[Google Scholar](#)]
  7. Mullany LC, Darmstadt GL, Katz J, Khatri SK, Leclercq SC, Adhikari RK, et al. Risk of mortality subsequent to umbilical cord infection among newborns of southern Nepal: cord infection and mortality. *Pediatr Infect Dis J* (2009) 28(1):17–20. doi:10.1097/INF.0b013e318181fb4c
  8. Ambe JP, Bello M, Yahaya SJ, Omotara BA. Umbilical cord care practices in Konduga Local Government Area of Borno State North atern Nigeria. *Internet J Trop Med* 2009;5(2): 1540-2681.
  9. Soofi S, Cousens S, Imdad A, Bhutto N, Ali N, Bhutta ZA. Topical application of chlorhexidine to neonatal umbilical cord for prevention of omphalitis and neonatal mortality in rural district of Pakistan: a community-based cluster-community randomized trial. *Lancet*.2012 Mar 17; 379(9820):1029-36. doi:10.1016/S0140-6736(11)61877-1.
  10. Imdad A, Mullany LC, B qui AH, EL Arifeen S, Tiesch JM, Khatri SK, et al. The effect of umbilical cord cleansing with chlorhexidine on omphalitis and neonatal mortality in community settings in developing countries: a meta-analysis. *BMC Public Health*. 2013;13 Suppl 3(Suppl 3) : S15. doi: 10.1186/1471-2458-13-S3-S15.
  11. Monebenimp F, Enganemben MM, Chelo D, Foumane P, Kamta C, Kuaban C. Mothers' knowledge and practice on essential newborn care at health facilities in Garoua city, Cameroon. *Health Sci Dis.*,2013, 14(2):1–6.
  12. Abhulimhen-Iyoha BI, Ibadin MO. Determinants of cord care practices among mothers in Benin city, Edo State, Nigeria. *Niger J Clin Pract* (2012) 15:210–3. doi:10.4103/1119-3077.97320
  13. Shew DD, Afolaranmi TO, Egbodo CO, Musa J, Oguche S, Bode-Thomas F. Methylated Spirit versus chlorhexidine gel: A randomized non-inferiority trial for prevention of neonatal umbilical cord infection in Jos, North- Central Nigeria. *Niger J Clin Pract*.2021 May; 24(5):762-769. Doi: 10.4103/njcp.njcp\_535\_20.
  14. World Health Organization (WHO). WHO Recommendations on Postnatal Care of the Mother and Newborn. (2013). Available from:<http://apps.who.int>
  15. Nigeria Federal Ministry of Health (FMOH). Save the Children, Saving Newborn Lives in Nigeria: Newborn Health in the Context of the Integrated Maternal, Newborn and Child Health Strategy. 2nd ed. Abuja: JHPIEGO, 2011. p. 41–7.
  16. Osuorah DI C, Ekwochi U, Onah S, Bernarsd EE. Umbilical Cord Care Practices and Incidence of Febrile Illnesses in the First Month of Life among Newborns-A Population-Based Study. *British Journal of Medicine & Medical Research*, 2015 5(11): 1422–30.
  17. World Health Organization. Newborn deaths decrease but account for the higher share of global child deaths. WHO 2012. [https://www.who.int/mediacentre/news/release/2011/newborn-deaths\\_20110830/en/index.html](https://www.who.int/mediacentre/news/release/2011/newborn-deaths_20110830/en/index.html) (accessed November 2012)
  18. Zulfiqar AB, Jai KD, Rajiv B, Joy EL, Rehana AS, Vinod KP, et al. Can Available Interventions End Preventable Deaths in Mothers, Newborn Babies, and Stillbirths, and at What Cost? *The*

- Lancet*, 2014, 384 (9940): 347–70.
19. World Health Organization. Postnatal Care of the Mother and Newborn 2013.” World health organization. World Health Organization. Postnatal Care of the Mother and Newborn 2013. World Health Organization.
  20. Federal Ministry of Health, Save the Children. *Saving Newborn Lives in Nigeria: Newborn Health in the Context of the Integrated Maternal, Newborn and Child Health Strategy*. 2nd Edition. Abuja: JHPIEGO, 2011.p.41-7.
  21. Mullany LC, Darmstadt GL, Khatry SK, Katz J, LeClerq SC, Shrestha S, et al. Topical applications of chlorhexidine to the umbilical cord for prevention of omphalitis and neonatal mortality in southern Nepal: a community-based, cluster-randomised trial. *Lancet*. 2006 Mar 18;367(9514):910-8. doi: 10.1016/S0140-6736(06)68381-5.
  22. Shwe DD, Abok II, Diala UM, Egbodo C, Toma BO, Nathan S, et al. Methylated spirit versus 4% chlorhexidine gel in neonatal umbilical cord infection: A short report of a randomized, open labelled, parallel-group trial. *Niger J Paediatr* 2018;45 (2):118–122.