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Incidence and risk factors for clinical omphalitis among neonates in Eastern Uganda using chlorhexidine gel for cord care: a community-cohort study

John Wogabaga¹, Kathy Burgoine^{2†}, Abel Kakuru^{1†}, Brendah Nambozo^{1*}, Martin Chebet^{3,4}, Josephine Tumuhamy⁵, Benon Wanume¹, Faith Oguttu³, Milton W. Musaba⁶, Agnes Napyo⁷, Solomon Wani³, Peter Olupot-Olupot⁸, Andrew D. Weeks⁹, Thorkild Tylleskär¹⁰ and David Mukunya¹

Abstract

Background Omphalitis is a bacterial infection of the umbilicus and/or surrounding tissues, occurring primarily in the neonatal period. Whereas it is known to be a major route of localized and often systemic infection, studies describing incidence and risk factors remain scanty, especially in resource limited settings where the condition is thought to be common. We assessed the incidence and risk factors for omphalitis among neonates born to women who received a birth kit containing chlorhexidine for umbilical cord care after birth in Eastern Uganda.

Trial registration for the parent study The BabyGel trial was registered in the Pan African Clinical Trial Registry –(PACTR202004705649428 Registered 1 April 2020, <https://pactr.samrc.ac.za/>).

Methods We conducted a community-based cohort study between January 2021 and June 2023. This study was nested within the BabyGel trial. Our outcome of interest was clinical omphalitis, defined as purulent discharge from the umbilical cord stump within the first twenty-eight days of life as witnessed by a study midwife. Data were analyzed using Stata version 17.0. Bivariable and multivariable analyses were conducted using Cox proportional hazard regression models to estimate hazard ratios (HR) of selected exposures and time to omphalitis.

Results A total of 2052 neonates were enrolled; half of which were female (51.1%). The incidence of omphalitis was 3.0% (62/2052; 95% confidence interval (CI): 1.9%, 4.4%). The incidence rate of omphalitis was 1.6 cases per 1000 person days (95% CI: 1.1, 2.3). Neonates born at home were twice as likely to develop omphalitis as those born in a health facility (adjusted hazards ratio (AHR) 1.99; 95% CI: 1.01, 3.9).

[†]Kathy Burgoine and Abel Kakuru contributed equally to this work.

*Correspondence:
Brendah Nambozo
262nbrendah@gmail.com

Full list of author information is available at the end of the article



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Conclusion The incidence of omphalitis among neonates in Eastern Uganda was low. Home births carried twice the risk for omphalitis. Use of chlorhexidine coupled with close follow-up of neonates in the community by health workers and community health workers might have reduced the risk of omphalitis.

Keywords Omphalitis, Neonate, Chlorhexidine, BabyGel, Neonatal sepsis, Newborn, Low-resource setting

Introduction

Omphalitis is bacterial infection of the umbilicus often with involvement of surrounding tissues and primarily occurs in the neonatal period [1]. Sub-Saharan Africa (SSA) has the highest neonatal mortality in the world, at 27 deaths per 1,000 live births [2]. In Uganda, the neonatal mortality is 22 deaths per 1000 live births [3] and infections are one of the leading causes of these deaths [4]. Infection of the umbilical cord stump, maybe a route of entry for pathogenic bacteria into the bloodstream that may progress to neonatal sepsis, death or lifelong complications such as poor growth, cerebral palsy and neurodevelopmental delay [5–8]. Omphalitis is associated with an estimated mortality rate between 7 and 15% with an average case fatality risk of up to 13% [9].

The incidence of omphalitis varies across settings, for instance, studies in high resource settings have reported rates as low as 0.7% [10]. On the other hand, the rates in low resource settings are as high as 8% for neonates born in hospital and 22% for those born at home [11, 12]. Furthermore, a recent cohort study in Uganda among 769 neonates found 8.5% incidence of omphalitis [7]. Elsewhere within sub-Saharan Africa, a study among 540 newborns in Kenya reported an incidence of omphalitis of 23% [13]. The high rates of omphalitis in low resource settings have been associated with application of unhygienic substances on the umbilical cord for example baby powder, animal dung, butter, ghee, soot, and plant extracts are applied to the umbilical cord [14–17].

In 2016, the Ministry of Health in Uganda started to promote the use of chlorhexidine gel for umbilical cord care as an intervention to reduce the prevalence of unhygienic umbilical cord care practices and subsequently omphalitis [10]. Possibly in response to this, neonatal mortality decreased slightly from 27 deaths per 1,000 live births in 2016 [18] to 22 deaths per 1,000 live births in 2022 [3]. However, anecdotal observations report continued cases of omphalitis among neonates where chlorhexidine has been used or provided. It is not known whether umbilical cord care practices have changed as a result of chlorhexidine being provided. It is against this background that we assessed the incidence and risk factors for omphalitis among neonates in a community cohort where chlorhexidine was provided to all participants as part of their birthing kit.

Methods

Study design

We performed a cohort study between January 2021 and June 2023.

Study setting

This study was nested within the BabyGel trial (PACTR202004705649428 Registered 1 April 2020, <https://pactr.samrc.ac.za/>) [19]. BabyGel is a cluster-randomized trial in Eastern Uganda where 72 clusters are randomized in a two-arm design with rural villages as units of randomization. A total of 5932 pregnant women were recruited from 34 weeks of gestation. All women and infants received standard antenatal and postnatal care including a birth kit (Maama Kit) and a 20 g tube of 7.1% chlorhexidine digluconate dermal gel (equivalent to 4% chlorhexidine). All participants were instructed to apply the chlorhexidine daily to the cord after bathing until the cord falls off. Women in the intervention group additionally receive six liters of alcohol-based hand rub and training on its use [20], but they were not included in this study.

Recruitment and follow-up

The community health workers within the study villages identified pregnant women at ≥ 34 weeks of gestation and informed the research midwives. The research midwives went to the villages, screened the pregnant women for eligibility, and recruited all who met the trial inclusion criteria. All recruited participants received the above-mentioned Maama Kit with chlorhexidine gel. After birth, the research midwives conducted physical follow-up visits within 48 h of birth, at day 7, and day 28 postpartum. They also performed telephone follow-up interviews on day 14. During the physical follow-up visits, the research midwives assessed the neonate for various health indicators including signs of omphalitis. Pictures of the umbilical cord were taken and reviewed by the trial medical officers and the trial clinical team.

Study population

Our study participants were neonates in the comparator arm of the BabyGel trial.

Inclusion criteria

We included live-born neonates born to mothers in the comparator arm of the BabyGel trial who were physically examined by the research midwives.

Exclusion criteria

We excluded neonates born with abdominal congenital anomalies such as omphalocele, gastroschisis, and bladder exstrophy.

Sample size estimation

The sample size was calculated using Open-Epi (<http://www.openepi.com>). We assumed an incidence of omphalitis of 27%, as observed in a study conducted in Western Uganda [21]. We further assumed a precision of 5% and a design effect of 2.0. This gave us a total sample size of 606 participants. At the time of data collection, we had access to complete data of 2052 participants, so we used all the available data as this would not result in any added costs, and increasing our sample size would improve the precision of our estimates, especially for the multivariable analyses.

Study variables

Outcome variable

Our primary outcome was omphalitis defined as the presence of pus on the umbilical cord stump at any time within the first 28 days of life as observed by the research midwives. We defined the time to omphalitis as the age in days of the neonate when they got their first episode of omphalitis. To minimize information bias, we validated interviewer observations with photographs of the umbilical cord taken with Android tablets. Two Medical officers, including the principal investigator, reviewed the photographs and where there was disagreement, a third medical officer was invited to review. A total of 81/2052 (4.0%) had redness around the cord. However, due to the dark skin nature of our population, this was difficult to assess and verify both clinically and on the photographs. As such, we used presence of pus to define omphalitis [7].

Exposure variables

Our key exposure variable was home birth. Additional exposures were: socio-demographic characteristics including maternal age, maternal education, residence, marital status, father's education, economic status, maternal parity, sex and birth weight. Clinical factors included maternal parity, place of birth, mode of delivery, antenatal care (ANC) visits. Neonatal characteristics such as sex of the child, birth weight.

Data collection procedures

Eighteen trained and experienced research midwives collected data at baseline and during follow-up visits using electronic questionnaires in the REDCap software (Vanderbilt University, Tennessee, USA, <https://www.project-redcap.org/>) on tablets. The completed questionnaires were saved on the tablets and uploaded onto a secure server daily. At initial recruitment into the

BabyGel trial, we collected data on the maternal social demographic factors. Furthermore, we collected data on antenatal attendance, place of birth, birthweight, sex, and cord care practices during follow-up visits.

Data analysis

We analyzed data using Stata version 17.0 (StataCorp LLC, College Station, Texas, United States of America). We summarized continuous variables in terms of means and standard deviations if they were normally distributed, and medians with corresponding interquartile ranges if they were skewed. We summarized categorical variables in terms of frequencies and percentages. We estimated the incidence of omphalitis by dividing the number of neonates who developed omphalitis by the population of neonates at risk during the first 28 days of life. The time to omphalitis was estimated using the Cox proportional hazards regression model with frailty at the cluster (village) level. Mothers/neonates that were lost to follow-up were included as censored observations. The total person-time contributed by each participant was the number of days from birth to omphalitis, loss to follow-up, death, or referral. Kaplan-Meier curves were used to graphically describe survival across places of birth. We conducted bivariable analyses using the Cox proportional hazard regression model to determine the association between omphalitis and various exposures including social demographic factors, social economic factors and clinical factors. This estimated the hazard ratios and their corresponding 95% confidence intervals. In multivariable analysis, we included home birth and other factors that were associated with omphalitis in the literature. These factors included maternal education, maternal age, mode of delivery, number of ANC visits, economic status, residence, sex and birth weight. In the causal model, we included home birth as the main exposure and other factors that are known to be potential confounders such as maternal age, maternal education, father's education, economic status and residence derived from a directed acyclic graph (DAG) (Fig. 1).

We calculated a concordance index to check the predictions of our model using Stata's *estat concordance* test, and this showed a high Harrell's C value (0.68), signifying that our model performed well. We then tested the proportional hazards assumption using the proportional hazard test in Stata (*estat phtest, detail*). Consequently, we also generated log-log plots to visually assess the violation of the proportional hazards assumption. We used Stata's *stphplot, by(var)* command to draw the log-log plots. All variables met the proportional hazard assumption.

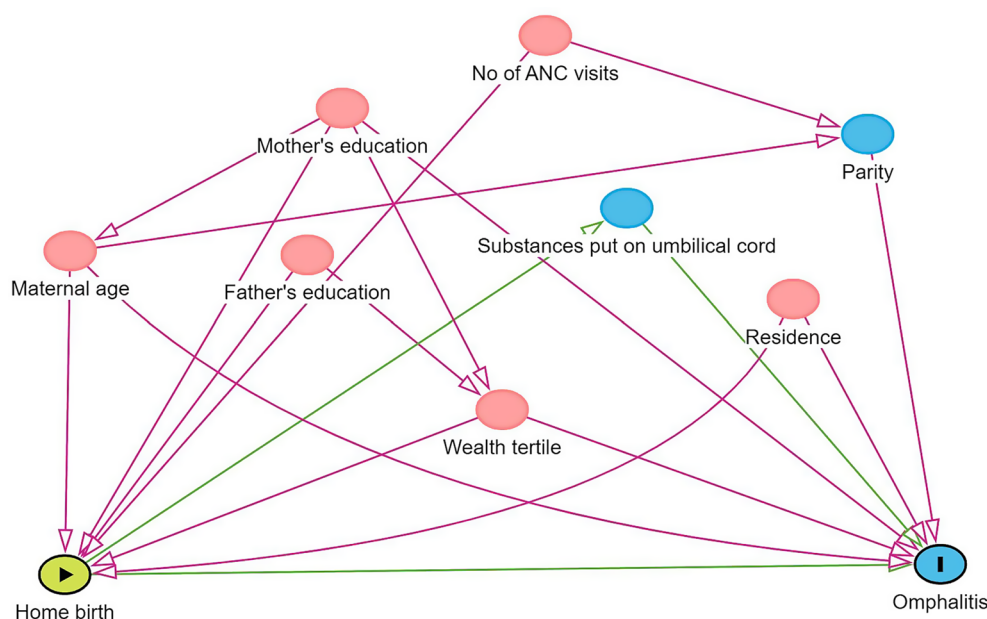


Fig. 1 DAG showing minimal sufficient adjustment sets used for estimating the total effect of home birth on omphalitis

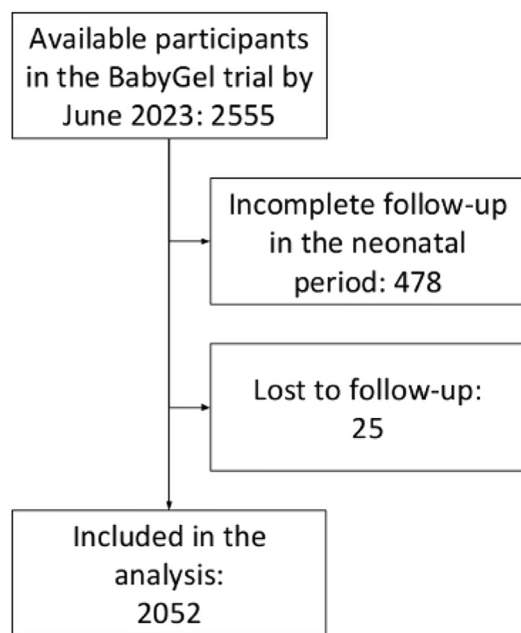


Fig. 2 study profile of the participants

Table 1 Socio-demographic characteristics of the mother and father to neonates in Eastern Uganda

Characteristics	Frequency (n)	Percentage (%)
Maternal age (years)		
14–19	428	20.9
20–24	683	33.3
25–29	458	22.3
30–34	298	14.5
35+	185	9.0
Maternal education		
None/Primary	1402	68.3
Secondary and more	650	31.7
Residence		
Peri-urban	384	18.7
Rural	1668	81.4
Marital status		
Single	230	11.2
Married	1822	88.8
Fathers' education		
None/Primary	1037	50.5
Secondary and more	1015	49.5
Wealth tertiles		
Poorest	772	37.8
Moderate	588	28.8
Richest	680	33.3

Results

Participant characteristics

Of the 2555 participants in the comparator arm of the BabyGel trial as of June 2023, we included 2052 (80.3%) mother-baby pairs. The remaining 478 were excluded because the neonates were younger than 28 days and did not have all follow-up data (Fig. 2). Twenty-five participants were loss to follow up. The mean age of the mothers was 24.9 ± 6.0 years. Less than a quarter of the participants were less than 20 years of age with the majority

aged 20–24 years (Table 1). Two-thirds of mothers had attained only a primary level of education, almost all of the participants were married and the majority resided in the rural communities (Table 1).

Perinatal characteristics of the mothers and their neonates

The majority of the participants 1334/2052 (65.3%) attended antenatal care 4 to 7 times. Slightly more than half 1079/2052 (52.7) of the participants had given birth to at least 2–5 children. Most mothers had vaginal births 1913 /2052 (93.2%) and gave birth at a health care facility (Table 2).

Incidence of omphalitis

Out of the 2052 neonates that were followed up until the end of the neonatal period, 62 developed clinical omphalitis, giving an incidence of 3.0% (62/2052; 95% CI: 1.9%, 4.4%). The incidence rate was 1.6 cases per 1000 person days (95% CI: 1.1,2.3) (Fig. 3).

Distribution of social-demographic characteristics among neonates with and without omphalitis

Out of the 62 neonates with omphalitis, slightly more than two thirds 69.4% (43/62) were born to women who had no or primary education. Less than a half were from the poorest wealth tertile 40.3% (25/62). (Table 3).

Substances put on the cord

At 48 h, seven participants put substances other than chlorhexidine on the cord. At day seven, six participants put substances other than chlorhexidine on the cord. At day 14 only four participants put substances other than chlorhexidine on the cord. At day 28, five substances other than chlorhexidine on the cord (Table 4).

Risk factors of omphalitis among neonates

Neonates of women who gave birth at home were twice as likely to develop omphalitis as those who gave birth at a health facility (adjusted Hazard Ratio [aHR] = 1.99; 95% CI: 1.01, 3.91) (Table 5).

Association between home birth and omphalitis among neonates

In the exploratory model, children born at home were twice as likely to develop omphalitis compared to children born at the health facility (aHR = 1.98; 95% CI: 1.01, 3.9) (Table 5). Similar observations were seen in the model adjusting for the confounders highlighted in Fig. 1, (aHR = 1.91; 95% CI: 0.98, 3.71).

Discussion

Our study assessed the incidence and risk factors for omphalitis among neonates born to women who received a birth kit containing chlorhexidine for umbilical cord care after birth in Eastern Uganda. The incidence of omphalitis was 3.0% and neonates born at home were twice as likely to develop omphalitis as those born in a health facility.

Table 2 Perinatal characteristics of the mothers and their neonates in Eastern Uganda

Characteristics	Frequency (n)	Percentage (%)
Maternal		
Parity		
1	612	29.9
2–5	1079	52.7
5+	357	17.4
Place of birth		
Health facility	1729	84.3
Home	323	15.7
Mode of delivery		
Vaginal birth	1913	93.2
Cesarean-section	139	16.8
Antenatal care Visits		
< 4	631	30.9
4–7	1334	65.3
8+	79	3.9
Neonatal characteristics		
Birth weight (kg)		
< 2.5	53	4.5
2.5–4.0	1078	91.3
> 4.0	50	4.2
Sex of the child		
Male	1003	48.9
Female	1047	51.1

*Kg; kilogram

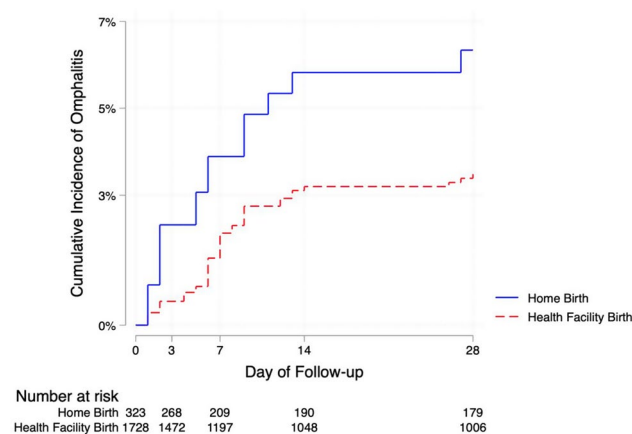


Fig. 3 Cumulative incidence of omphalitis across levels of the place of birth among neonates in Eastern Uganda

Incidence of omphalitis

The incidence of omphalitis in the neonatal period in this study was 3.0%. our finding is much lower than anticipated in view of data reporting the incidence of omphalitis of >10% in most SSA settings [7, 21, 22]. The lower incidence in our study could be attributed to several factors. Firstly, all participants received chlorhexidine for umbilical cord care, and chlorhexidine is a broad-spectrum antimicrobial that substantially reduces bacterial colonization of the cord stump if applied early [23,

Table 3 Distribution of social-demographic characteristics among neonates with and without omphalitis in Eastern Uganda

Variable	No cord infection <i>n</i> = 1990	Cord infection present <i>n</i> = 62	<i>p</i> value
Maternal age (years)			
4–19	419 (21.1%)	9 (14.5%)	0.26
20–24	667 (33.5%)	16 (25.8%)	
25–29	441 (22.2%)	17 (27.4%)	
30–34	285 (14.3%)	13 (21.0%)	
35+	178 (8.9%)	7 (11.3%)	
Maternal education			
None/primary	1359 (68.3%)	43 (69.4%)	0.86
Secondary and more	631 (31.7%)	19 (30.7%)	
Fathers Education			
None/Primary	998 (50.2%)	39 (62.9%)	0.05
Secondary and more	992 (50.0%)	23 (37.1%)	
Wealth Tertiles			
Poorest	747 (37.8%)	25 (40.3%)	0.73
Moderate	573 (29.0%)	15 (29.2%)	
Richest	658 (33.3%)	22 (35.5%)	
Residence			
Peri-urban	376 (18.9%)	8 (12.9%)	0.23
Rural	1614 (81.1%)	54 (87.1%)	
Parity			
0	597 (30.1%)	15 (24.2%)	0.15
1–4	1039 (52.3%)	40 (64.5%)	
5+	350 (17.6%)	7 (11.3%)	
Antenatal care Visits			0.64
< 4	611 (30.8%)	20 (32.3%)	
4–7	1293 (65.2%)	41 (66.1%)	
8+	78 (3.9%)	1 (1.6%)	
Place of birth			
Health facility	1683 (84.6%)	46 (74.2%)	0.03
Home	307 (15.4%)	16 (25.8%)	
Mode of delivery			
Vaginal birth	1856 (93.3%)	57 (91.9%)	0.68
Cesarean-section	134 (6.7%)	5 (8.1%)	
Birth weight (kg)			
< 2.5	52 (4.6%)	1 (2.4%)	0.3
2.5–4.0	1038 (91.1%)	40 (97.6%)	
> 4.0	50 (4.4%)	0 (0.00%)	
Sex of the neonate			0.67
Male	971 (48.8%)	32 (51.6%)	
Female	1017 (51.6%)	30 (48.4%)	

24]. Our finding is similar to a community-based study in Nepal which observed a low incidence rate of 0.25 of omphalitis among those who used chlorhexidine gel for umbilical cord care [25]. This finding could imply that provision of chlorhexidine to mothers for cord care during the postpartum period could reduce the use of other unhygienic substances on the cord and consequently reduce the incidence of omphalitis.

Table 4 Substances other than chlorhexidine put on the cord of neonates in Eastern Uganda

Variables	No Omphalitis (<i>n</i> = 1990)	Omphalitis (<i>n</i> = 62)	Total (2052)
48 h			
Coconut oil	1	0	1
Colgate tooth paste	1	0	1
Herbal	1	0	1
Nothing	2	0	2
Tea leaves	1	0	1
Warm water with salt	1	0	1
Day 7			
Iodinated table salt	1	0	1
Papyrus Ash	1	0	1
Soot	0	1	1
Spirit	1	0	1
Toothpaste	1	0	1
charcoal	1	0	1
Day 14			
Cooking oil	0	1	1
Toothpaste	1	0	1
Warm salty water	1	0	1
Spirit	1	0	1
Day 28			
Cooking oil	0	1	1
Herbal remedies	1	0	1
Toothpaste	1	0	1
Warm salty water	1	0	1
Spirit	1	0	1

Secondly, the research midwives conducted three physical follow-ups at the homes of the participants and one telephone visit within the first 28 days. During the first visit after birth, the research midwives examined the umbilical cord and applied chlorhexidine if it was not yet applied. The research midwives also educated the mothers on newborn care. This could have contributed to the low incidence of omphalitis in our cohort. This could imply that interventions such as close follow-up of neonates within the neonatal period by community health workers or community midwives to ensure correct application of chlorhexidine could reduce omphalitis. Thirdly, the majority of the participants (82%) gave birth in a health facility with the help of a skilled birth attendant and in a clean environment which reduces the risk of omphalitis [26]. This is consistent with a study in India found the incidence of omphalitis in hospital-born babies to be as low as 2.3% [27].

Home births and omphalitis

Giving birth at home birth was associated with greater risk for omphalitis. Our finding is similar to those in India [27] and Oman [12] that also found an association between home births and increased risk for omphalitis. The possible explanation is that most of the home births

Table 5 Risk factors of omphalitis among neonates in Eastern Uganda

Variable	Unadjusted HR (95% CI)	P-value	Adjusted HR (95% CI)	P-value
Place of birth				
Health Facility	1		1	
Home	1.99 (1.04 to 3.79)	0.04	1.98 [1.01, 3.91]	0.048
Maternal Education				
None/Primary	1		1	
Secondary and more	0.91 (0.50 to 1.66)	0.76	1.08 [0.55, 2.11]	0.819
Wealth Tertiles				
Poorest	1		1	
Middle	0.79 (0.39 to 1.61)	0.515	0.84 [0.41, 1.72]	0.624
Richest	1.00 (0.52 to 1.94)	0.999	1.14 [0.57, 2.31]	0.71
Number of ANC Visits				
< 4	1		1	
4–7	0.87 (0.48 to 1.60)	0.66	0.96 [0.51, 1.79]	0.893
8+	0.30 (0.04 to 2.27)	0.24	0.31 [0.04, 2.38]	0.258
Low Birth Weight				
No	1		1	
Yes	0.70 (0.10 to 5.13)	0.73	0.79 [0.11, 5.86]	0.817
Maternal Age				
< 20	1		1	
20–24	1.03 (0.44 to 2.39)	0.94	1.13 [0.44, 2.86]	0.801
25–29	1.33 (0.56 to 3.17)	0.52	1.52 [0.55, 4.23]	0.42
30–34	2.00 (0.84 to 4.77)	0.12	2.27 [0.80, 6.40]	0.123
35+	1.08 (0.33 to 3.53)	0.9	1.10 [0.30, 4.10]	0.882
Father's Education				
None/Primary	1		1	
Secondary and more	0.67 (0.38 to 1.19)	0.17	0.59 [0.30, 1.14]	0.118
Residence				
Peri-urban	1		1	
Rural	1.12 (0.48 to 2.61)	0.79	1.12 [0.47, 2.69]	0.802
Mode of Birth				
Vaginal	1		1	
Caesarean	1.14 (0.41 to 3.20)	0.8	1.33 [0.46, 3.82]	0.6
Child Sex				
Boy	1		1	
Girl	0.85 (0.49 to 1.47)	0.561	0.87 [0.50, 1.52]	0.615

*HR; hazard ratio, CI; confidence interval, ANC; antenatal care

are conducted in unhygienic environments by either traditional birth attendants, relatives, or the mother herself [5, 28]. In addition, home births are usually accompanied by unsterile practices during umbilical cord clamping and cutting for example use of unsterile equipment and cord ligatures. Furthermore, poor hand hygiene and the application of unhygienic substances to the cord also increase the risk of omphalitis in neonates born at home [5, 29]. Therefore, there is a need to continue educating pregnant women and communities about the importance of giving birth in health facilities under the care of a skilled birth attendant.

Methodological discussion

Selection bias

Some participants had missing data on the outcome variable and these were excluded from analysis. This possibly introduced selection bias that could have underestimated or overestimated the incidence of omphalitis. Furthermore, some participants were lost to follow up and this could have introduced a selection bias; however, very few participants were lost to follow-up (less than 5%).

Information bias

We used only the presence of pus on the umbilical cord stump to diagnose omphalitis because redness and swelling were difficult to assess on black skin. Using only pus as a criterion increased the specificity of our diagnosis and reduced type 1 error (concluding that the child had omphalitis when in fact they did not have omphalitis). However, this might have increased the type II error (concluding that a child did not have omphalitis when in fact they had omphalitis) leading to underestimation of the incidence of omphalitis.

Confounding

To assess the association between home births and omphalitis, we adjusted for potential confounders using the Cox proportional hazards regression model. Potential confounders were derived from a directed acyclic graph. We believe the estimates obtained are close to the population parameters. However, we cannot rule out the effects of residual confounding introduced by unmeasured confounders and improper stratification of potential confounders.

Implications for practice

Our study appears to validate the Ugandan ministry of health policy of providing chlorhexidine to mothers and for postnatal care. This study also indicates that good outcomes that can be achieved if there is a systematic intervention to provide chlorhexidine and regular postnatal visits, even in very rural areas.

Conclusion

We found a low incidence of omphalitis among neonates in a community cohort in Eastern Uganda that had chlorhexidine provided for umbilical cord care after birth. Home birth increase the risk of omphalitis. Our findings suggest that there is need to continue promoting health facility births during antenatal and postnatal care. In addition, use of chlorhexidine coupled with close follow-up of neonates in the community by health workers and community health workers might have reduced the risk of omphalitis.

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Author contributions

JW, KB, AK and DM conceived the idea and drafted the first draft manuscript, DM analyzed the data, BN, MC, JT, BW, FO, MM, AN, SW, POO, AW, and TT drafted part of the manuscript, interpreted results, reviewed the subsequent versions.

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Data availability

The datasets used and/or analyzed during the current study will be available upon reasonable request from the chief investigator of the BabyGel trial ADW.

Declarations

Ethical approval and consent to participate

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. We obtained ethical approval from the Busitema University Research Ethics Committee (BUFHS-2022-45). The parent study also obtained ethical approval from the Research and Ethics Committee of the University of Liverpool (UoL004457), the Regional Committee for Medical and Health Research Ethics (REC-vest), Norway (#47004), and Cure Hospital Uganda (CCHU-REC/21/019). Written informed consent was obtained from all mothers before recruitment into the trial. The mothers also consented to taking photographs of their babies' umbilical cords in the informed consent form. After birth, the research midwives explained why they needed to take pictures of umbilical cord. Mothers were again asked if they were willing for the pictures of the baby's cord to be taken. No pictures were taken without consent.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Author details

¹Department of Community and Public Health, Busitema University, Mbale, Uganda

²Department of Pediatrics, Mbale Regional Referral Hospital, Mbale, Uganda

³Department of Research, Sanyu Africa Research Institute, Mbale, Uganda

⁴Department of Pediatrics, Busitema University, Mbale, Uganda

⁵Makerere University Hospital, Makerere University, Kampala, Uganda

⁶Department of Obstetrics and Gynecology, Busitema University, Mbale, Uganda

⁷Department of Nursing Sciences, Kabale University, Kabale, Uganda

⁸Mbale Clinical Research Institute, Mbale, Uganda

⁹Sanyu Research Unit, Department of Women's and Children's Health, University of Liverpool, Liverpool Women's Hospital, Liverpool, UK

¹⁰Centre for International Health, Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway

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