ABSTRACT

The efficacy of alcohol or water in promoting umbilical cord separation was compared in a randomized controlled trial. Rates of skin colonization between groups were also evaluated on three occasions. Time to cord separation, rates of colonization, and species of organisms that colonized were compared between groups. Of 148 participants, 136 (92%) completed the protocol. Cords that were cleaned with sterile water separated more quickly than those cleaned with alcohol ($t = 3.15$, $p = 0.002$). Between-group differences in colonization rates were not found ($F = 1.59$, $df = 2$, $p = 0.205$). Umbilical or other infections did not occur. Bacterial colonization of the umbilical area and surrounding skin occurs over time in healthy term neonates. Cleaning with alcohol will increase the length of time from birth to cord separation but will not prevent colonization of the umbilical area.

ABRÉGÉ

Dans une étude sur échantillon aléatoire et contrôlé, on a comparé l'efficacité de l'alcool à celle de l'eau pour favoriser la séparation du cordon ombilical. Les taux de colonisation bactérienne cutanée entre les groupes ont également été comparés à trois reprises. Le temps de séparation du cordon, les taux de colonisation et les types d'organismes colonisateurs ont aussi été comparés entre les groupes. Sur les 148 participants, 136 (92 %) ont complété le protocole de recherche. Les cordons ombilicaux nettoyés avec de l'eau stérile se sont séparés plus rapidement que ceux nettoyés avec de l'alcool ($t = 3,15$, $p = 0,002$). On n'a pas relevé de différences dans les taux de colonisation des différents groupes ($F = 1,59$, $D = 2$, $p = 0,205$). Il n'y a pas eu d'infections ombilicales ou autres. La colonisation bactérienne de la région ombilicale et de la peau adjacente apparaît avec le temps chez les nouveau-nés, nés à terme et en bonne santé. Le nettoyage avec de l'alcool augmente le temps de séparation du cordon et ne prévient pas la colonisation bactérienne de la région ombilicale.

Cleaning Solutions and Bacterial Colonization in Promoting Healing and Early Separation of the Umbilical Cord in Healthy Newborns

Jennifer M. Medves, RN, MN,¹ Beverley A.C. O'Brien, RN, DNSc²

The umbilical cord stump should separate from a healthy newborn within two weeks of birth.¹ Caregivers recommend an antibacterial solution for umbilical cleaning that aids cord separation and reduces the incidence of umbilical infection.²⁻¹⁰ Antibacterial solutions vary as does the time to cord separation.¹¹⁻¹³ The risk of umbilical infection has been reduced as a consequence of early discharge programs.¹⁴ New parents have many skills to learn and a complicated umbilical cord cleaning regime may be redundant if the aim is to promote early separation and healing of the umbilicus.

No solution has been shown to maintain a sterile field around the umbilical stump and this may not be desirable since bacterial colonization is thought to aid in the cord separation process.¹⁵ Although the American Academy of Pediatrics recommends that mild soap be used to clean the skin of babies, most institutions ignore this policy and use a variety of antibacterial solutions both for bathing and treating the umbilical stump.¹⁶ This may not be desirable since an antimicrobial agent may actually delay the time to cord separation.^{14,15,17,18}

The incidence of omphalitis is very rare, and that of fasciitis even rarer.¹⁹ Observation of the umbilical area may be more appropriate than cleaning. No Canadian study was found that evaluated the most commonly used antibacterial—

alcohol. Therefore the purpose of this investigation was to evaluate differences in time to cord separation and bacterial colonization using either alcohol or water to clean the cord area. We hypothesized that there would be no between-group difference in either time to cord separation or colonization rates.

Colonization was defined as the growth of bacterial organisms which include normal skin flora, coliforms, and mixed faecal flora, as well as potential pathogens such as *Staphylococcus aureus* (*S. aureus*) and group B beta haemolytic streptococci (GBS). An umbilical cord infection was defined as the presence of foul-smelling exudate, and/or pus cells, and/or a raised and reddened area of skin around the umbilicus. Sterile water was applied to the umbilical area with a 20cm x 10cm Kendall dressing while sterile alcohol was applied by using a Webcor antiseptic isopropyl alcohol pad.

METHODS

One hundred and forty-eight healthy term infants born at a tertiary care hospital in western Canada between 28 May 1996 and 15 July 1996 were included in the study. One hundred and thirty-six (92%) infants completed the protocol, including one set of twins. The parents of infants expected to meet inclusion criteria were given an information sheet when they were admitted in active labour. Consent was obtained from parents who volunteered to participate within three hours of birth. Infants were assigned to one of two treatment groups using a blocked randomization method. Consent and information sheets were available in five languages, however consent forms signed by the parents were all in English, except for one

1. Faculty of Nursing, University of Alberta
2. Associate Professor, Faculty of Nursing, Member of Perinatal Research Centre, University of Alberta

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Correspondence and reprint requests: Jennifer M. Medves, Graduate Student, 3rd floor, Clinical Sciences Building, University of Alberta, Edmonton, AB, T6G 2G3, E-mail: jmedves@gpu.srv.ualberta.ca

family who signed a consent form in Chinese. Parents of infants in both groups were shown a short video that was developed for the study and demonstrated general cord care. The gestational age of all infants randomized into the study was at least 37 completed weeks (except one infant who was 36 weeks and 5 days). All infants had apgars of at least 7 at 5 minutes.

Sample

The final sample size was determined through power analysis whereby a between-group difference of 12 hours was considered the least amount of time needed to produce an effect which could be considered clinically significant. By accepting the conventional risks for Type I ($\alpha = 0.05$) and Type II ($\beta = 0.2$) errors, a minimum of 50 infants were required for each group. In order to allow for attrition, an *a priori* decision was made to enroll 74 infants in each group. Infants remained in the treatment group to which they were assigned, even if the parents did not follow the treatment (i.e., intent to treat). Two families admitted they did not follow the protocol. Other reasons for dropping out of the study included going out of town ($n=2$), being advised by health care professionals to use a different solution ($n=3$), water swabs making "the baby scream" ($n=1$), water swabs kept the "cord too moist" ($n=1$), being admitted to Neonatal Intensive Care Unit ($n=1$), and cord remaining unseparated after six weeks ($n=1$). There were no between-group differences in demographic characteristics for either group assignment or rate of colonization and species of bacteria isolated.

Study protocol

The first skin swab was taken at the time of randomization and prior to the first bath. The institution's policy was to bathe each infant in Hibitane® (chlorhexidine gluconate 2%) within the first six hours of life. The second swab was taken on Day 3, generally in the infant's home. Parents were asked to contact the investigator by pager on the day that the cord separated to allow a home visit to confirm cord separation and to take the third and final swab.

TABLE I T- tests for Independent Samples of Group Assignment			
Variable	Number of Cases	Mean Hours	Standard Deviation
Group one (sterile water)	65	252	89
Group Two (sterile alcohol)	71	314	136
t-value 3.15, two-tailed significance 0.002 mean difference = 62 hours			

Umbilical cord colonization methodology

A template of sterile gauze was used to ensure the swabbed area was similar for each infant. Swabs were taken at the base of the cord in a rolled method as advocated in a central line catheterization study.²⁰ The swabs were placed immediately into a transport medium and carried by hand to a clinical microbiology laboratory. Each swab was inoculated onto a sheep blood agar plate and was then streaked with a sterile spreader. The agar plates were incubated at 39°C for 24 to 48 hours and microbial growth was assessed as scant, light, moderate, or heavy. All results were recorded and quantified by the same research microbiology technologist who was blind to group assignment.

Between-group differences in time to umbilical cord separation were calculated using a t-test. Colonization rates over time were analyzed using repeated measures analysis of variance (ANOVA). The SPSS 7.0 statistical package was used to analyze the data.

Results of cord separation time by group

The mean difference in time to cord separation for the infants whose cords were cleaned with sterile water was 61.7 hours less than those infants whose cords were cleaned with sterile alcohol ($t = 3.15$, $df = 121$, $p = 0.002$) (Table I). Although the variance about the mean was greater for the group treated with alcohol, normal distribution was assumed because of the large sample size.

Parents may not have noticed the exact time of cord separation. However, as the diapers of newborns are changed approximately six times a day, the time of cord separation was accurate to within four to six hours for each infant. There was no reason to suspect that one group would be

more diligent than the other in reporting the time of cord separation. The only set of twins in the study were randomized into different groups. The twin whose cord was cleaned with sterile water separated 146 hours (6.1 days) after birth, while the twin whose cord was cleaned with sterile alcohol separated 170 hours (7.1 days) after birth.

Results of skin colonization studies

Colonization was assigned values of no growth, scant, light, moderate, and heavy growth. Using repeated measures ANOVA, differences were not found in colonization rates between the two groups ($F = 1.59$, $df = 2$, $p = 0.205$).

The first swab was taken prior to the first bath and cord cleaning. The results serve as a baseline measure. All the swabs ($n=147$) were analyzed for quantity and species of organism. In each group, slightly over half did not colonize (water 53%, alcohol 56%). Significant between-group differences in species of organism were not found of those that did colonize with mixed flora, coagulase negative staphylococci, and diptheroids. The second swab was taken in the infant's home (except for infants still hospitalized because they were delivered by LSCS). Sterile specimens were obtained from 19% of the water group and 27% of the alcohol group.

We intended to take the final swab ($n = 136$) within 12 hours of cord separation. However, the umbilical areas of 34 infants were swabbed more than 24 hours following cord separation due to a delay in notification by parents. One specimen had no growth. Mixed skin flora, diptheroids, and coliforms were more prevalent in the sterile water group while coagulase negative staphylococci (CNS) was more prevalent in the alcohol group.

DISCUSSION

We found that cleaning the cord with alcohol compared to water lengthened the mean time to umbilical cord separation by 2-3 days. This means that there is a longer time in which a potential port for infection exists. Sterile alcohol compared to sterile water as a cleaning solution did not reduce the level of skin colonization. The length of time to cord separation for the combined data was found to be similar to other North American studies; 9.8 days,⁶ 10.3 days,⁵ 10.9 days,²¹ and 15 days.²² The reason why umbilical cords separate later in North America than in the rest of the world is not easily explained, but frequency of care, duration of hospitalization, and humidity may be factors.²²

All infants were bathed in Hibitane® (chlorhexidine gluconate 2%) following birth in the newborn nursery. Chlorhexidine gluconate has been associated with a reduction in the rate of colonization of *S. aureus*, group B and G streptococci, and *Escherichia coli*.²³ Smales noted that time to cord separation increased from 10 to 20 days when cords were cleaned with 4% chlorhexidine instead of an iodine preparation.²⁴ If bacterial contamination is required to assist in cord separation, it may be that the Hibitane® bath cleansed the newborn skin of the bacteria required for colonization to begin and this may explain why so many specimens obtained on Day 3 had no microbial growth.

Parents are usually asked to keep the cord dry by folding the diaper below the umbilicus until the cord separates and the umbilicus heals. This may be more easily accomplished with disposable diapers that have special umbilical indents in the newborn size. In Northern Canada babies are usually well dressed, and the time to cord separation may be delayed because the cord is almost never completely exposed.

The colonization studies supported our hypothesis. Colonization is a function of

time and the sterile alcohol did not eradicate any particular group of organisms. Our findings also support the hypothesis that treating the cord with alcohol delays umbilical cord separation. There is no reason to suspect this would not be the case with any antimicrobial solution. As newborns spend a limited amount of time in the hospital following birth and parents have many adjustments to make, there is no evidence to support the continued use of alcohol for routine umbilical cord care. Health care professionals in the community can monitor the progress of cord separation and intervene as necessary. A monetary saving would occur if routine umbilical cord care was discontinued. In terms of nursing time, if 10 minutes is set aside to teach cord care at \$20 an hour, \$16,000 will be saved per year at the study hospital which has about 4,800 births a year. Since the unhealed umbilicus is a potential site for infection, a delay in time to separation and healing should be avoided.

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