

Umbilical Cord Care in Premature Infants: The Effect of Two Different Cord-Care Regimens (Salicylic Sugar Powder vs Chlorhexidine) on Cord Separation Time and Other Outcomes

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ABSTRACT. *Objectives.* To evaluate the effect of 2 cord-care regimens (salicylic sugar powder vs chlorhexidine as a 4% detergent water solution) on cord separation time and other outcomes in preterm infants.

Methods. A prospective, randomized, controlled trial was conducted on 244 preterm newborns with a gestational age of <34 weeks and a birth weight of <2500 g. All preterm newborns were enrolled, regardless of their health condition. We excluded from the study infants whose conditions during the first hours of life required the catheterization of umbilical vessels. We also excluded from the general statistical analysis all newborns who had their programmed cord-care regimen changed because of the presence or the suspicion of omphalitis. On arrival at our neonatal intensive care unit or neonatal special care unit, infants were bathed thoroughly with a soap solution (Saugella, Guieu, Italy), and the umbilical cord (UC) was treated with 1 of the 2 antiseptic products chosen for the study. The stump was then folded and covered with common sterile, dry gauze and kept in place by an elastic net. Until cord detachment and at every diaper change, the cord stump was cleaned with sterile water and treated with the same product initially used for first-time cord care. On the third day of life, we obtained an umbilical swab either from the base of the cord or from the umbilicus if the cord was already sloughed. Six weeks after birth, during hospitalization or during a follow-up visit if already discharged, all infants had a medical examination to check the umbilicus area. Cord separation time, changing of the programmed cord-care regimen, death, omphalitis, sepsis, cord bleeding, nurses' opinion on treatments efficacy, and UC colonization were measured.

Results. The cord separation time was significantly lower in infants who were treated with salicylic sugar powder (6 ± 2 days) than in infants who were treated with chlorhexidine (9 ± 2 days). The programmed cord-care regimen was changed in a significantly higher number of newborns in the chlorhexidine group (17) than in the salicylic sugar group (3). None of the newborns died, and we found only sporadic cases of sepsis (1 patient in each group) and omphalitis (1 patient in the chlorhexidine group). A significantly higher percentage of nurses were satisfied with the salicylic sugar powder treatment (98%) than with the chlorhexidine treatment (67%), notwithstanding a more frequent occurrence of slight cord

scar bleeding in the salicylic sugar group (7.8%) than in the chlorhexidine group (4%). The rate of negative umbilical swabs was significantly higher in infants treated with salicylic sugar powder (73.1%) than with chlorhexidine (53%).

Conclusions. In neonatal intensive care units and neonatal special care units of developed countries, salicylic sugar powder can be used effectively and safely for UC care of preterm infants. *Pediatrics* 2003;112:e275–e279. URL: <http://www.pediatrics.org/cgi/content/full/112/4/e275>; umbilical cord, preterm newborn, time of detachment, bacterial colonization, omphalitis.

ABBREVIATIONS. UC, umbilical cord; WHO, World Health Organization; NICU, neonatal intensive care unit; NSCU, neonatal special care unit.

The umbilical cord (UC) is an important bacterial colonization site.¹ A possible consequence of bacterial colonization is cord stump infection, a factor that can greatly increase morbidity and mortality in developing countries.² In the 1940s, the introduction of nurseries in hospitals increased the risk of colonization and infections in developed countries as well.² Consequently, the application of rigorous cord-care programs became necessary at birth, during hospitalization, and on discharge. In 1998, the World Health Organization (WHO)² established cord-care recommendations at birth and after discharge from the hospital that are currently being observed in developed countries. A thorough hand-washing constitutes an important measure in the prevention of cord stump contamination,^{2,3} but the tendency of medical and paramedical attendants to perform this simple hygienic procedure is notoriously low.^{4,5} This is why several investigators^{6–8} recommend the application of an antiseptic on the UC regardless. Although the American Academy of Pediatrics considers no antiseptic treatment to be superior to any other, they confirm its utility.⁹ Finally, the WHO established that in hospital nurseries, it is probably best to apply a topical antimicrobial to the cord stump after cutting the cord and once a day for the first 3 days.² It is important to remember, however, that antiseptic treatment delays cord detachment^{6,7,10,11}; subsequently, the cost of postnatal care may increase unnecessarily.¹²

Preterm infants are at higher risk of infection, partly because of their prematurity and partly be-

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cause they are exposed to a higher risk of nosocomial infections.¹³ Given the higher risk of bacterial sepsis in these infants, use of antiseptics has the potential of reducing nosocomial infection.¹³ This is why we use cord-care antiseptic treatment in our neonatal intensive care unit (NICU) and neonatal special care unit (NSCU). The WHO² and Zupan and Garner¹³ emphasized the need for studies including preterm infants; however, we could not identify any trials that studied UC care in this group of infants.

The main purpose of this study was to compare the effect of 2 different cord-care regimens in relation to cord separation time in preterm infants. We also considered the following outcomes: changing of programmed cord-care regimen, bacterial umbilical colonization, omphalitis, sepsis, death, stump bleeding, and nurses' opinion regarding the 2 treatments' efficacy. For the UC care, we compared 2 products: salicylic sugar powder, which we recently showed to give excellent results in terms of early UC detachment and other outcomes in term infants,¹⁴ and chlorhexidine, 1 of the 4 suggested antimicrobials found in the WHO cord-care drug list.²

METHODS

Sample Calculation

After preliminary experiments, we calculated that, with 80% power and 5% significance, we would need 32 neonates for detecting a 3-day difference in cord detachment average time when expected average values were 7 and 10 days with an expected standard deviation of 3 days for both groups, and 203 neonates for detecting a 0.2 difference in colonization rate when expected proportion was 0.5 and 0.7. We decided to include 244 infants to cover potential problems with late exclusions.

Protocol

A prospective, randomized study was conducted on all premature infants who were hospitalized consecutively in our NICU or in our NSCU between October 1, 2001, and October 31, 2002. All newborns with a gestational age of <34 weeks and a birth weight of <2500 g were considered eligible for enrollment, regardless of their health condition. We excluded from the study only infants whose conditions during the first hours of life required the catheterization of umbilical vessels. All newborns whose programmed cord-care regimen changed because of the presence or suspicion of omphalitis were not excluded from the study; their data were analyzed separately because we thought that the change in the cord-care treatment would have erroneously modified the time of cord detachment and the umbilical colonization rate.

Procedures

All newborns who were admitted to the study were exposed to the following regimen: on arrival at the NICU or NSCU, infants were bathed thoroughly with a soap solution (Saugella, Guieu, Italy), and the UC was treated with 1 of the 2 antiseptic products chosen for the study; the stump was then folded and covered with common sterile, dry gauze and kept in place by an elastic net. Until cord detachment and at every diaper change (before every meal), the cord stump was cleaned with sterile water and treated with the same product initially used for first-time cord care.

The 2 different regimens were 1) chlorhexidine as a 4% detergent water solution and 2) salicylic sugar powder (97% powdered sugar, 3% salicylic acid). Our hospital pharmacy service prepared both the chlorhexidine solution and the salicylic sugar powder. The 2 products used were subject to weekly testing, and the cultures never found contamination.

The patients were selected to enter either of the 2 groups randomly by means of the sealed envelope technique. The caregivers were not blinded as to allocation because the cord stumps looked different depending on which treatment group the infant was in.

On the third day of life, we obtained an umbilical swab either from the base of the cord or from the umbilicus if the cord was already sloughed. The swab was then sent to our laboratory and placed in a culture on blood agar Columbia, blood agar CNA, Sabouraud agar, and desoxycholate agar (KIMA, Padova, Italy). In the case of the presence of bacterial growth, the bacteria were identified in the case of both monocolonization and pluricolonization. Laboratory personnel were kept uninformed of the subjects' cord-care regimen.

For evaluating the 2 groups' homogeneity at entry, gestational age, birth weight, sex, way of delivery, Apgar score, and cord arterial pH were recorded for each neonate. On discharge, we collected the following information: cord stump separation time, omphalitis, sepsis, death, and cord bleeding. We also collected information regarding antibiotic therapy, infections, jaundice treated with phototherapy, number of days and kind of phototherapy, location in incubators or cots, weight loss at the moment of cord detachment, and number of days of parenteral infusion. At the end of the study, nurses were asked, by anonymous questionnaire, the following question: "Are you satisfied with salicylic sugar powder/chlorhexidine for cord-care treatment?" Six weeks after birth, during hospitalization or during a follow-up visit if already discharged, all infants had a medical examination to check the umbilicus area.

Arterial cord blood was studied at birth for determining the value of pH (ABL 625 Radiometer, Copenhagen, Denmark). Diagnosis of omphalitis was made on the basis of clinical evidence of cord infection: contemporary presence of erythema, edema, smell, and/or purulent discharge from the stump.¹³ Suspicion of omphalitis was made on the basis of the presence of 1 among the following signs of inflammation of the cord or of the tissues surrounding the cord: erythema (<2 cm), edema, and tenderness.² An area of erythema >2 cm was considered diagnostic for omphalitis. Infants who developed omphalitis or suspicion of omphalitis were programmed to interrupt the initial cord-care regimen and to be treated locally with 1% basic fuchsin and intravenously with antibiotics (ampicillin and gentamycin) or, for suspicious cases, locally with 1% basic fuchsin alone. Sepsis was diagnosed as a clinical syndrome of systemic illness with bacteremia. We defined the need for phototherapy and its length according to the practice guideline of the American Academy of Pediatrics.¹⁵ A Photograph-Therapie 800 Heraeus unit (Dräger, Lübeck, Germany) was used for conventional phototherapy; a BiliBlanket phototherapy system (Ohmeda, Louisville, KY) was used for fiber-optic phototherapy.

Informed consent was obtained from the parents of all infants who were considered eligible for enrollment, and the study was approved by our institutional review board.

Statistical Analysis

Statistical analyses were performed by using Microsoft Excel. For numerical variables, *t* test was used to compare all possible pairs of mean values, after assessing homogeneity of variance by means of the Fisher exact test. The χ^2 test was applied for the categorical variables using the chlorhexidine-treated infants as "expected." *P* < .05 was considered statistically significant.

RESULTS

During the examined period, 244 newborns were deemed admissible to the study. Eleven of these infants were successively excluded because, in the first 2 to 3 days of life, they needed umbilical catheterization because of worsening of general conditions or enteral feeding intolerance. None of them showed signs of omphalitis. The sample analyzed therefore consisted of 233 preterm newborns, that is, 95.5% of infants admitted; 52.4% (122) were girls and 47.6% (111) were boys. We excluded from the general statistical analysis 20 newborns whose programmed cord-care regimen changed because of the presence or the suspicion of omphalitis. In the group that was treated with salicylic sugar powder, 3 newborns had their programmed cord-care regimen changed; in the

group that was treated with chlorhexidine, 17 newborns had their programmed cord-care regimen changed ($P = .0004$). Among infants who were excluded from general statistical analysis, in the salicylic group, we did not find cases of omphalitis, whereas in the chlorhexidine group, we found 1 case of omphalitis; no statistical analysis was performed because of the particularly small number of cases found in the 2 groups examined. The final sample analyzed therefore consisted of 213 preterm newborns, or 87.3% of infants initially admitted.

The principal epidemiologic and clinical characteristics of the 2 study groups at entry are shown in Table 1. The 2 groups considered were shown to be homogeneous in that no significant statistical differences were found with regard to weight, gestational age, sex, way of delivery, Apgar score, and cord pH.

Data pertaining to some factors of patients' clinical course, which could have implication in the cord separation time or UC colonization, are shown in Table 2. Also regarding these parameters, we did not find significant differences between the 2 groups. Considering the entire group of 213 newborns, we did not find any correlation between the cord separation time and the length of phototherapy ($P = .980$; data not shown) and between the cord separation time and the weight loss at the moment of cord detachment ($P = .602$; data not shown).

Table 3 shows data regarding the cord separation time and the other outcomes in the 2 groups of newborns. There were no cases of omphalitis or death in any of the infants studied. With regard to cases of sepsis, no statistical analysis was performed because of the particularly small number of cases found in the 2 groups examined. The 2 patients with sepsis, 1 in each group, had a birth weight of <1000 g and were mechanically ventilated for several days; 1 of them developed a pneumothorax requiring insertion of a chest tube. Blood culture of both newborns was positive for *Staphylococcus aureus*. The umbilicus was normal, and the umbilical swab was negative.

Regarding UC colonization, our study shows that 73.1% of the infants who were treated with salicylic sugar had a negative umbilical swab compared with 53.4% of the chlorhexidine group ($P = .003$). Mono-

TABLE 1. Epidemiologic and Clinical Characteristics of the 2 Study Groups at Entry*

	Salicylic Sugar Powder	Chlorhexidine	<i>P</i>
No. of patients	112	101	
Weight (g; mean \pm SD)	1862 \pm 417 (range, 980–2500)	1866 \pm 406 (range, 920–2450)	.94
Gestational age (wk)	33 \pm 2	34 \pm 2	.16
Female	57.1 (%)	49.5 (%)	.11
Male	42.9 (%)	50.5 (%)	
Vaginal	62.5 (%)	67.3 (%)	.33
Cesarean	37.5 (%)	32.7 (%)	
Apgar score	9 \pm 1	9 \pm 1	.91†
Cord pH	7.33 \pm 0.1	7.32 \pm 0.1	.28

SD indicates standard deviation.

* Values presented as number, mean \pm SD, or percentage.

† χ^2 .

TABLE 2. Factors With Possible Implication in Cord Separation Time or UC Colonization of the 2 Study Groups*

	Salicylic Sugar Powder	Chlorhexidine	<i>P</i>
No. of patients	112	101	
Jaundice†	41.1 (%)	31.7 (%)	.20
Length of phototherapy (h)	41 \pm 21	44 \pm 19	.54
Conventional phototherapy	40 (%)	40.6 (%)	.16
Fiber-optic phototherapy	60 (%)	59.4 (%)	
Parenteral infusion (h)	10 \pm 27	7 \pm 21	.48
Incubator‡	47.3 (%)	42.6 (%)	.08
Cot‡	52.7 (%)	57.4 (%)	.58
Antibiotic therapy	44.6 (%)	33.7 (%)	.14

* Values presented as number, mean \pm SD, or percentage.

† Jaundice needing phototherapy.

‡ From birth to cord detachment.

TABLE 3. Data Regarding Cord Separation Time and Other Outcomes*

	Salicylic Sugar Powder	Chlorhexidine	<i>P</i>
No. of patients	112	101	
Cord separation time (d)	6 \pm 2	9 \pm 2	<.0001
Sepsis (<i>n</i>)	1	1	-
Omphalitis (<i>n</i>)	0	0	-
Death (<i>n</i>)	0	0	-
Cord bleeding†	7.8 (%)	4.0 (%)	.027
Nurses' opinion on treatments efficacy‡	98 (%)	67 (%)	<.0001

* Values presented as number, mean \pm SD, or percentage.

† Less than 2 days.

‡ Forty-nine nurses were interviewed about the 2 cord-care regimens efficacy. They were asked: "Are you satisfied with salicylic sugar powder/chlorhexidine for cord-care treatment?"

colonization was statistically higher ($P = .008$) in the chlorhexidine group (41.5%) than in the salicylic group (24.3%). Pluricolonization (2 or 3 organisms) was higher, but not significantly ($P = .516$), in the chlorhexidine group (5.1%) than in the salicylic group (2.6%).

Between the 2 study groups, we did not find significant differences in the cord colonization for the 3 microorganisms (*Streptococcus hemolyticus* group B [$P = .395$], *Escherichia coli* [$P = .091$], and *Staphylococcus aureus* [$P = .203$]) that are thought to cause the most UC infections in hospital nurseries.^{2,3,16} We found significantly higher percentages of colonization of *Staphylococcus non-aureus* and *Enterococcus* in chlorhexidine group than in the salicylic group. We did not find significant differences in the percentage of colonization of the other microorganisms between the 2 study groups.

DISCUSSION

This is the first study to evaluate the effect of 2 cord-care regimens on cord separation time and other outcomes in preterm newborns. In this work, we studied the efficacy of salicylic sugar powder, which we have shown to be effective in the term infant.¹⁴ We compared it with chlorhexidine, which the WHO considers one of the most commonly used antimicrobials for UC care.²

Cord treatment may alter cord separation

time.^{6,7,10,11} Because the umbilical stump is a common means of entry for systemic infection, delay in cord detachment may risk bacterial entry²; furthermore, it may increase the cost of postnatal care.¹² Our study showed that the use of an antiseptic product in powder form is related to a shorter cord separation time than an antiseptic product in liquid form (Table 3). These data confirm what was already shown in other studies^{6,10,13,14,17–19} and emphasize the important role of the dehydrating action in the cord detachment process.^{2,17,20} The importance of dehydration is confirmed by the relatively rapid cord sloughing in newborns who were treated with natural drying.¹⁴ We showed that the shortest cord separation time was obtained with the use of salicylic sugar powder (6.2 days), which is concordant with the data in the study of Branchi et al (5.5 days)¹⁷ and of Pezzati et al (5.6 days),¹⁴ who studied term infants. The extreme effectiveness of this medicament in powder form is probably related to the combination of the keratolytic effect of salicylic acid and the dehydrating action of the sugar.^{14,17} The mean time of cord detachment for chlorhexidine (9.2 days) was significantly higher; it was similar to other antiseptic solutions, such as 1% basic fuchsin (10.3 days) and triple dye (11.6 days), but much lower than 70% alcohol (16.9 days), which we studied in term infants.¹⁴ To identify other factors that might affect cord separation time, we evaluated the possible role of length of parenteral infusion, phototherapy, and maximum weight loss at the moment of cord detachment in the entire study population (data not shown). None of them showed significant influence. These data support the idea that length of parenteral infusion alone and phototherapy alone do not affect cord separation time. Because general hydration is connected to weight loss,^{14,17} it is clear that local—and not general—dehydration influences cord detachment.

We think that it is very important to consider the group of 20 newborns whose programmed cord-care regimen changed because of the presence or suspicion of omphalitis. Regarding these data, the efficacy of salicylic sugar powder was significantly higher than chlorhexidine. The 19 newborns whose programmed cord-care regimen changed because of suspicion of UC infection (3 newborns only in the salicylic group) were treated successfully only by local treatment with 1% basic fuchsin, and they did not develop infections or sepsis. These data, together with the more rapid sloughing of the UC in the salicylic group, are related directly to the significantly higher percentage of nurses who were satisfied with the use of salicylic sugar powder treatment than with the chlorhexidine treatment. However, when detachment time was shorter, there was a more frequent occurrence of cord scar bleeding. Importantly, however, in all cases, there was a light blood loss of short duration (<2 days), which did not heighten nurses' concerns.

In our study, we did not record any cases of death or notice any statistically significant differences with regard to sepsis or omphalitis, as only a few cases were observed. It is, at any rate, interesting to note

that the 2 cases of sepsis were not related to UC infection and that the 1 case of omphalitis found in the chlorhexidine group was corrected easily by changing the local antiseptic cord-care regimen (1% basic fuchsin) and by intravenous injection of antibiotics (ampicillin and gentamycin).

Studies conducted in developed countries show that the use of antiseptic products on the UC manifoldly reduces the bacterial colonization rate in hospital nurseries.^{11,21–24} The relationship between bacterial colonization reduction and the reduction of umbilical infections is less clear.^{2,13} If an infant is kept with its mother (by rooming-in), then the bacteria colonizing the newborn come mostly from its mother's normal skin flora and are predominantly nonpathogenic. On the contrary, in hospital nurseries, the cord is frequently colonized with potential pathogens of human origin.² Once colonized, the umbilicus acts as a reservoir of bacteria that may cause cross-infection.² Even if the factors that cause colonization of the cord stump to progress to infection are poorly understood, we think that, especially in preterm infants, an increased cord colonization is a disadvantage. This is why the WHO recommends that hospital nurseries apply a topical antimicrobial,² despite that this cord treatment may destroy the resident flora and facilitates invasion by pathogenic bacteria. As we said, no study had been conducted on preterm infants. Preterm newborns are at higher risk of infection partly because of their prematurity and partly because they are exposed to a higher risk of nosocomial infections.¹³ Given the higher risk of bacterial sepsis in these infants, use of antiseptics has the potential for reducing nosocomial infection.¹³ In our study, we have shown that the use of salicylic sugar powder is related to a significantly higher negativity of colonization rate (73.1%) than is chlorhexidine. Furthermore, we found a significantly higher monocolonization rate in the chlorhexidine group than in the salicylic group. These findings partially differ with respect to the lower negativity of colonization rate (43.7%) that we found in term infants who were treated with salicylic sugar powder.¹⁴ We think that it could be because of the major attention to hygienic procedures adopted with premature infants.

In terms of pluricolonization (2 or 3 microorganisms) and of contamination rates caused by *S aureus*, *E coli*, and *S hemolyticus* group B, we did not find significant differences between the 2 study groups because of the small sample examined. As a matter of fact, although pluricolonization in chlorhexidine group (5.1%) is roughly twice that in the salicylic group (2.6%), this difference could be considered significant (power = 0.8, α = 0.05) only in a population 8 times greater (2014) than ours (244). In expounding on these results, however, we cannot omit the importance that the specific bacterial flora residing in each hospital and the personnel's hygiene practices have in determining the UC contamination.³ Because we conducted a prospective and randomized study and infants from the 2 groups were in the same rooms and cared for by the same personnel units, we can exclude the possibility that differences

of bacterial colonization in the 2 groups might be related to significant differences in hospital flora or personnel's hygiene practices.

CONCLUSIONS

In 1998 the WHO² and in 2001 Zupan and Garner¹³ stated that studies regarding the care of the UC in the preterm newborns were lacking and called for research that includes this population. Our study shows that salicylic sugar powder allows for earlier cord detachment than chlorhexidine. The incidence of positive umbilical swabs is low, and it is significantly lower than chlorhexidine. This study demonstrates that, in NICUs and NSCUs of developed countries, salicylic sugar powder can be used effectively and safely for UC care of preterm infants.

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