

Efficacy of 10% povidone iodine versus 70% alcohol in umbilical cord care of newborn infants

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ABSTRACT

Objective To compare the effectiveness of 10% povidone iodine to that of 70% alcohol in umbilical cord care of newborn infants.

Methods This open label clinical trial was conducted in Pirngadi Hospital, Medan from July to September 2003. Newborn infants who fulfilled inclusion criteria were randomly allocated to umbilical cord care using 10% povidone iodine or 70% alcohol. The main outcome measures were omphalitis prevalence, microorganism colonization, and time to umbilical cord separation. Culture of the umbilical cord swab was taken in the first 48-72 hours after birth. The umbilical cord was observed daily during hospitalization and every other day after discharge until cord separation. Statistical analysis was done using chi-square test and independent t-test.

Results There were 54 infants in the povidone iodine group and 52 infants in the alcohol group. Omphalitis was absent in both groups. Fourteen percent of subjects in the povidone iodine group showed no microorganism growth, compared to 7% in the alcohol group. *Staphylococcus aureus* colonization was found in 10% of subjects in the povidone iodine group and 23% of subjects in the alcohol group. The prevalence of *Escherichia coli* colonization was 41% and 47% in the povidone iodine and alcohol groups, respectively. There was no statistically significant difference between both groups in bacterial colonization ($P=0.135$). Mean time to umbilical cord separation was 6.44 days in the povidone iodine group and 6.13 days in the alcohol group ($P=0.431$).

Conclusion These results suggest that 10% povidone iodine and 70% alcohol are equally effective in umbilical cord care of newborn infants [**Pediatr Indones 2005;45:198-202**].

Keywords: umbilical cord care, newborn, povidone iodine, alcohol

Umbilical cord infection (omphalitis) and neonatal tetanus continue to be important causes of neonatal morbidity and mortality in developing countries.¹ Infection of the umbilical stump caused by improper cord care and harmful cultural practices are the main reasons for the high frequency of neonatal tetanus in rural communities in the tropics.² The exact incidence of omphalitis is unknown. It appears to be relatively rare in developed countries, but is probably underreported as infants may be discharged early from hospital and not followed up at home.¹ In India, Faridi found that in 46.6% of infants hospitalized with sepsis, omphalitis was the source of illness.³ Watkinson and Guvene, as cited by Fletcher, reported that *Staphylococcus* was the most common cause of omphalitis in neonates born in the hospital.⁴

Umbilical cord care plays a pivotal role in preventing neonatal infections such as tetanus and sepsis.⁵ Care of the umbilicus is necessary to prevent it

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from serving as a culture medium for pathogenic microorganisms, such as *Staphylococcus aureus* or *Clostridium*. Several studies have shown that umbilical cord stump and the surrounding skin is the main source of staphylococcal colonization.^{6,7} Aseptic nursing, including aseptic technique and isolation, cannot prevent staphylococcal colonization and infection. Antiseptic measures may be necessary to reduce the amount of pathogenic bacterial colonization at the umbilical cord stump, which is a perfect reservoir for bacteria in neonates.^{5,6}

The purpose of this study was to compare the efficacy of 10% povidone iodine with that of 70% alcohol in umbilical cord care of newborn infants, with regard to omphalitis prevalence, microorganism colonization, and time to umbilical cord separation.

Methods

This was an open label clinical trial conducted in Pirngadi Hospital, Medan from July to September 2003. Ethical approval for this study was obtained from the Medical Ethics Committee of Pirngadi Hospital, Medan. Infants included in this study were fullterm newborns (born at gestational age of 37-42 weeks) who were healthy, without abnormality, and weighed 2500-4000 grams at birth, whose parent or guardian gave informed consent. Newborns who received antimicrobial therapy were excluded. Infants who fulfilled these criteria were divided into two groups based on a random number table. Infants in the first group received umbilical cord care using 10% povidone iodine. To infants in the second group, cord care was given using 70% alcohol. The required sample size was 48 for each group, using a 95% confidence interval, normal standard deviation of α of 1.960, normal standard deviate of β of 0.842, a proportion of 0.75 in the alcohol group and 0.95 in the povidone iodine group, and power of 0.8. After delivery, the umbilical cord was clamped and cut with sterile equipment until the length of the stump was 3 cm. After that, the umbilical cord was wrapped with sterile gauze soaked with antiseptic solution (10% povidone iodine or 70% alcohol).

On umbilical cord care, in the povidone io-

dine group, 5 ml of 10% povidone iodine was applied to the umbilical cord and the surrounding skin within a 5 cm diameter of the stump. The cord was then wrapped with sterile gauze. In the alcohol group, the umbilical cord was wrapped with sterile gauze soaked with 5 ml of 70% alcohol. Aseptic measures such as handwashing using clean water and soap, and using sterile equipment to cut the umbilical cord were done to avoid infection. The gauze was changed twice daily. Umbilical cord care was done by a well trained nurse. Data on gestational age, body weight, sex, and method of delivery were collected and recorded.

A swab of the base of the umbilical cord stump was done using a sterile cotton swab within 48-72 hours of delivery. The swab was transported in Stuart media to the Microbiology Department, Medical School, University of North Sumatra, for culture. The swab was then incubated in blood agar media and MacConkey media at a temperature of 37°C for 18-24 hours. The culture was then analyzed biochemically, macroscopically, and microscopically for microorganism colonization. The result was reviewed 24 hours later. We performed home visits every other day to observe infants already discharged from hospital. Such visits were done until the umbilical cord had separated. The umbilical cord was inspected for any redness, edema, or purulent discharge. Omphalitis was defined as redness and edema in the soft tissue surrounding the stump.⁸

Statistical analysis was done using chi-square test to compare the proportions of bacterial colonization and omphalitis between the two groups. The time to umbilical cord separation was compared using independent t-test.

Results

Of 112 neonates who fulfilled inclusion criteria, 5 were not studied because of non-compliance with the study protocol, consisting of 1 infant from the povidone iodine group and 4 from the alcohol group. One subject from the povidone iodine group was excluded due to antibiotic use. Hence, only 106 samples were studied, 54 in the povidone iodine group and 52 in the alcohol group. Characteristics of infants and their mothers are shown in **Table 1**.

TABLE 1. NEONATAL AND MATERNAL CHARACTERISTICS

	Povidone iodine (n=54)		Alcohol (n=52)	
	n	(%)	n	(%)
Sex				
male	29	(54)	29	(56)
female	25	(46)	23	(44)
Birth weight (grams)				
2500-3000	13	(24)	14	(27)
3050-3500	26	(48)	23	(44)
3550-4000	15	(28)	15	(29)
Method of delivery				
spontaneous	34	(63)	37	(71)
caesarean section	19	(35)	15	(29)
vacuum extraction	1	(2)	0	(0)
Person giving umbilical cord care at home				
mother	14	(29)	17	(36)
father	2	(4)	1	(2)
grandmother	14	(52)	13	(48)
midwife	15	(31)	13	(28)
other	4	(8)	3	(6)
Parity				
primiparous	19	(35)	19	(36)
multiparous	34	(63)	30	(58)
grande-multiparous	1	(2)	3	(6)
Mother's age (years)				
= 20	2	(4)	3	(6)
21-35	46	(85)	36	(19)
> 35	6	(11)	13	(25)
Mother's education level				
elementary school	7	(13)	4	(8)
junior high school	11	(20)	5	(10)
senior high school	21	(40)	29	(56)
diploma	7	(13)	6	(11)
university graduate	8	(15)	8	(15)

Baseline characteristics of the two groups were similar.

We found no omphalitis in both groups. Redness of the tissue surrounding the umbilical cord was found in 3/54 in the povidone iodine group and 5/52 in the alcohol group with no statistically significant difference ($P=0.429$) (Table 2).

Culture results of subjects in both groups are shown in Figure 1. Fourteen percent of the culture was sterile in the povidone iodine group versus 7% in the alcohol group. Colonization by *Staphylococcus aureus* occurred in 10% vs 23%, *Escherichia coli* in 41% vs 47%, and other microorganisms (*Klebsiella sp.*, *Proteus sp.*, *Citrobacter sp.*, *Enterobacter sp.*, *S. epidermidis*, *Candida albicans*) in 20% vs 13% of cultures in the povidone iodine and alcohol groups, respectively. There were no statistically significant differences between the two groups in terms of bac-

terial colonization ($P=0.135$).

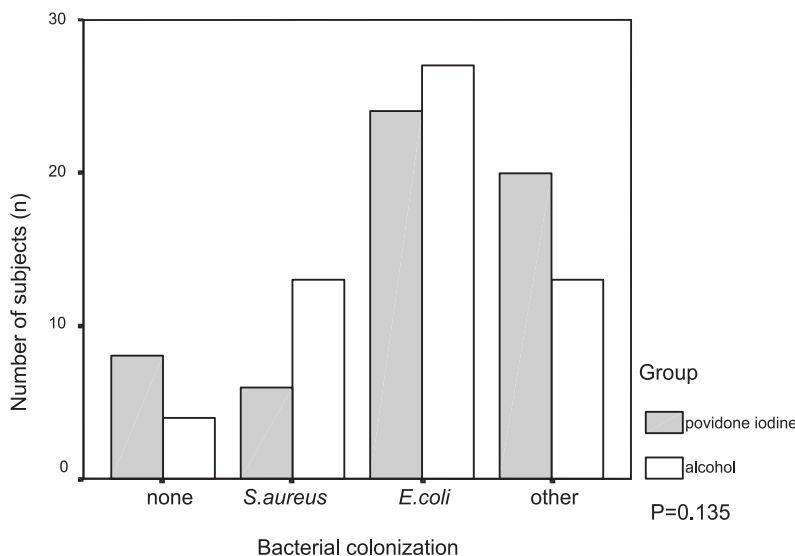
Time to separation of the umbilical cord was 6.44 days in the povidone iodine group and 6.13 days in the alcohol group, conferring no statistically significant difference ($P=0.431$). The time needed for separation of the umbilical cord ranged between 4 to 12 days in the povidone iodine group and 3 to 13 days in the alcohol group.

Discussion

No infant in this study developed omphalitis. There was no statistically significant difference in microorganism colonization between the two groups. *Escherichia coli* was the most common microorganism found in cultures from both groups, while *Staphylococcus aureus* was found in 10% and 23% of

TABLE 2. SIGNS OF INFECTION IN PERIUMBILICAL AREA

Condition of periumbilical area	Antiseptic Povidone iodine (n=54)		Alcohol (n=52)		P
	n	(%)	n	(%)	
Good	51	(94)	47	(90)	0.429
Not good					
Redness	3	(6)	5	(10)	
Edema	0	(0)	0	(0)	
Pus	0	(0)	0	(0)	
Total	54	(100)	52	(100)	

**FIGURE 1.** BACTERIAL COLONIZATION IN POVIDONE IODINE AND ALCOHOL GROUPS

cultures from the povidone iodine and alcohol groups, respectively. Fourteen percent of the cultures from the povidone iodine group showed no microorganism growth, compared to 7% in the alcohol group.

Janssen⁹ compared umbilical cord care using triple dye and alcohol as antiseptics with dry cord care without antiseptic agent in 766 infants. The umbilical cords of infants in the dry care group showed more colonization by *E. coli* (34.2% vs 22.1%) and *Staphylococcus aureus* (31.3% vs 2.8%). In addition, one case of omphalitis was found in the dry care group, compared to none in the antiseptic group. In 1975, Wong¹⁰ compared umbilical cord nursing with iodophor and triple dye and found no significant statistical difference in colonization by Group-B *Streptococcus* (GBS) between the two groups. Meberg¹¹ in 1985 reported a high rate of *Staphylococcus aureus* colonization (90%) in newborn

infants who did not receive antiseptic umbilical cord care after discharge, while in the group who received cord care using Hibiscrub[®] the colonization rate was 51%. Seeberg⁶ reported that umbilical cord care with 4% chlorhexidine effectively prevented and controlled staphylococcal and streptococcal infections in newborns during hospitalization and after discharge. Twenty point nine percent out of 1041 infants who received daily umbilical cord care with 70% ethanol suffered from omphalitis. There was a significant reduction in omphalitis incidence after nursing with chlorhexidine. Pildes¹² showed that triple dye is an effective antiseptic to reduce staphylococcal colonization in neonates. Wald¹³ found that triple dye was more effective in preventing GBS colonization than unspecified umbilical cord nursing. Johnson¹⁴ concluded that bacitracin is safe and effective to control staphylococcal colonization and infection during hospitalization. Umbilical cord care

without antiseptic measures (dry cord care) was not effective in reducing staphylococcal infection and colonization during hospitalization.

In our study, the mean umbilical cord separation time was 6.44 days in the povidone iodine group vs 6.13 days in the alcohol group. Golombek¹⁵ found that umbilical cord care using alcohol enabled faster cord separation (10 days) compared to triple dye (13 days). A study by Triasih¹⁶ comparing the effectiveness and safety of colostrum with that of alcohol found that umbilical cord separation time was 188.0 ± 68.8 hours in the alcohol group. Hidayati¹⁷ reported no significant difference in umbilical cord separation time in the povidone iodine and alcohol groups (5.91 days vs 7.45 days). Dore¹⁸ found that umbilical cord separation time was 9.8 days in the alcohol group vs 8.16 days in the natural drying group.

The limitation of our study is that, having been an open label clinical study, the nurse who changed the sterile gauze was not the same for every patient. However, in this study all umbilical cord examinations were done by the same observer and specimens for culture were taken by the same microbiologist.

We conclude that 10% povidone iodine and 70% alcohol are equally effective in the umbilical cord care of newborn infants, as shown by comparable microorganism colonization and time to cord separation.

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