A Randomized Study of 3 Umbilical Cord Care Regimens at Home in Thai Neonates: Comparison of Time to Umbilical Cord Separation, Parental Satisfaction and Bacterial Colonization

Sangkae Chamnanvanakij, MD*, Kesanee Decharachakul, MD*,
Phonphat Rasamimaree, MD*, Nirun Vanprapar, MD*

** Department of Pediatrics, Phramongkutklao Hospital*

Objective: *To compare time to cord separation, parental satisfaction and bacterial colonization, among 3 regimens of cord care at home.*
Study design: *Randomized controlled trial.*
Material and Method: *Term infants were randomly assigned based on cord care regimens at home: 1) triple dye, 2) alcohol, and 3) no antiseptic agent. Timing of cord separation, and parental satisfaction were evaluated during the first month of age.*
Results: *185 infants were recruited. Time to cord separation in infants of group 1 was significantly longer than in group 2 ($p = 0.036$) and group 3 ($p = 0.003$). The satisfaction scores of group 1 were significantly lower than those of group 2 and group 3. 180 culture specimens were performed and positive in all but none had omphalitis.*
Conclusion: *Triple dye delayed time to cord separation and was less satisfactory. The authors conclude that using alcohol or dry clean could be alternative ways of umbilical cord care at home.*

Keywords: *Umbilical cord care, Time to cord separation, Triple dye, Alcohol, Clean cord care*

J Med Assoc Thai 2005; 88(7): 967-72
Full text. e-Journal: *http://www.medassocthai.org/journal*

The World Health Organization (WHO)[1] recommends that for a newborn infant born in hospital, a topical antimicrobial agent should be applied to the umbilical stump at birth and for the first few days to prevent bacterial colonization and cross-infection. For umbilical cord care after discharge from hospital, clean cord care is sufficient and the application of an antiseptic agent is not required. Although clean umbilical cord care is one of the standard practices in Western countries, this practice is less common in Thailand. Concerning that high humidity and poor maternal education may increase the risk of umbilical infection, prolonged use of antimicrobial agents until umbilical cord separation has been practiced for decades. Since triple dye is effective against staphylococcus[2-7] and appropriate for preventing umbilical infection in hospital, it becomes the most common antimicrobial agent used for umbilical cord care in Thailand. The problems of using triple dye in newborn infants are purple staining of skin and delayed time to cord separation[7-10]. Alcohol is an alternative antimicrobial agent widely used around country, though, it is less effective against staphylococcus[6,11]. To establish a proper regimen of umbical cord care in Thai neonates, The authors conducted a study to compare time to cord separation, parental satisfaction and bacterial colonization when using triple dye in hospital and following with different regimens of cord care at home: triple dye, alcohol or no antiseptic agent.

Correspondence to : Chamnanvanakij S, Department of Pediatrics, Phramongkutklao Hospital, 315 Rajavithee Rd, Bangkok 10400, Thailand. Phone: 0-2354-7660 ext 94109, 94180, Fax: 0-2248-4191, E-mail: sangkae@hotmail.com

Material and Method

The present study was a randomized controlled trial. The eligible criteria included term newborn infants (gestational age $\geq$ 37 weeks) born at

Phramongkutklao Hospital, Bangkok, Thailand. Informed consent was obtained from parents before enrollment. Infants who had a high risk of infection such as low birth weight (< 2500 grams), one minute Apgar score < 8, a maternal history of prolonged rupture of membrane, chorioamnionitis or meconium-stained amniotic fluid were excluded. Sick infants admitted in the neonatal intensive care unit or stayed in hospital for longer than 4 days were also excluded. Infants whose mothers had history of poor antenatal care were not included.

During staying in a hospital nursery, umbilical stump was applied using triple dye once daily until discharge. At the time of discharge, eligible infants were randomly assigned into one of three groups based on antiseptic agents used for umbilical cord care at home. Simple randomization was performed using a randomization table. Treatment allocation was concealed in separate well-sealed opaque envelopes. In group 1 and 2, triple dye or alcohol was applied on umbilical stump once daily, respectively. In group 3, clean water was used for cleaning the umbilicus without using any antiseptic agent.

Maternal education before discharge included umbilical cord care as assigned, observation the signs and symptoms of infection. Mothers were instructed to record the cord separation date and time and also to complete the questionnaire on satisfaction.

Home visits took place within 7 days post-discharge for monitoring maternal compliance and for umbilical swab cultures. At one month of age, infants were followed-up at a pediatric outpatient clinic. The data of time to umbilical cord separation, satisfaction, and complications was collected.

The outcome was analyzed by using "intention to treat" in purpose. The primary outcome measurment was time to cord separation in days. Parental satisfaction was assessed by using a questionnaire which consisted of 5 items (stained-color, odor, dryness of umbilical stump, ease of application and timing of cord separation). The satisfaction scores of each item were graded into 5 levels.

Sample size was calculated to detect the difference in mean cord separation time among three groups by using multiple comparisons. The significant difference of mean time to cord separation was 3 days. After compensation for 20% dropout rate, the number of subjects in each group was 60.

The study was reviewed and approved by an ethic committee at Phramongkutklao Hospital.

Statistical analysis

Differences of mean time to cord separation among 3 groups were identified by using ANOVA. Multiple comparisons to determine the differences between 3- pair means were analyzed using Dunnett T3' s procedure. The mean difference was significant at the 0.05 level. To determine the effect of covariates such as mode of delivery, birth weight, and bathing, multiple regression analysis was performed.

Non-parametric test, Kruskal Wallis, was used to identify difference of rank scores among groups. The differences of satisfaction scores between triple dye and other regimens were analyzed by using Mann-Whitney u test at the significant level of 0.025.

The rate and distribution of bacterial colonization were analyzed using descriptive statistics. Comparison of bacterial colonization among groups was analyzed using Chi-square test. Prevalence of infection and omphalitis were compared using Fisher's exact test.

Results

During the study period, there were 734 infants born at Phramongkutklao Hospital. 694 infants were admitted in a well-baby nursery. Umbilical infection was diagnosed in two of them on the second day of life. Therefore, the incidence of omphalitis during the study period was 0.29% among normal term infants. One hundred and eighty-five term infants were recruited into the present study. The means of maternal age, gestational age, birth weight and length of hospital stay were not different among groups. There were no differences in the percentages of primiparous mothers, male infants, breast feeding and bathing. However, cesarean section rate was higher in the triple dye group compared to other groups (Table 1).

Deviations from the study protocols in 4 infants were reported due to 2-day errornous uses of triple dye or alcohol. No other antiseptic agent outside of the protocol was used before cord separation. The data of time to cord separation, parental satisfaction scores was completely collected in all infants. Umbilical swab cultures were performed in 180 (97.3%) infants. The failure to collect 5 cultures was due to temporary move to rural areas at the time of home visit.

The mean time to cord separation in triple dye, alcohol and no antiseptic group were 16.25 ± 6.29, 13.79 ± 4.26 and 13.12 ± 3.82 days, respectively (Table 2). The mean time to cord separation in infants of the triple dye group was significantly longer than

Table 1. Characteristics of infants (n = 185)

Characteristics	Triple dye (n = 63)	Alcohol (n = 60)	No antiseptics (n = 62)
Maternal age (yr)*	26.97 (5.92)	26.88 (6.54)	25.45 (5.73)
Primiparous (%)	22 (34.9)	24 (40.0)	28 (45.2)
Cesarean section (%)	14 (22.2)	4 (6.7)	2 (3.2)
Male (%)	35 (55.6)	39 (65.0)	32 (51.6)
Gestational age (wk)*	38.78 (1.11)	38.68 (1.30)	38.50 (1.17)
Birth weight (g)*	3180 (361)	3171 (321)	3104 (304)
Length of stay (d)*	2.45 (0.66)	2.50 (0.62)	2.25 (0.49)
Bathing (%)	58 (92.1)	58 (96.7)	55 (88.7)
Breast feeding (%)	62 (98.4)	58 (96.7)	62 (100)

* Data presented as mean (standard deviation)

Table 2. Descriptive statistics of time to cord separation (day)

Group	n	Mean	SD	95%CI	Minimum	Maximum
Triple dye	63	16.25	6.29	14.67, 17.84	7.43	34.81
Alcohol	60	13.79	4.26	12.69, 14.89	3.71	27.78
No antiseptics	62	13.12	3.82	12.15, 14.09	4.13	23.21

Comparison of mean time to cord separation between triple dye and others assessed by ANOVA, p = 0.001

those of alcohol (p = 0.36) and no antiseptic groups (p = 0.003). There was no difference of time to cord separation compared between alcohol and no antiseptic group (p = 0.74). The mean difference of time to cord separation compared between triple dye vs alcohol and triple dye vs no antiseptic agent were 2.46 days (16.25-13.79 days) (95%CI 0.12, 4.80) and 3.13 days (16.25-13.12 days) (95%CI 0.88,5.39), respectively. Multiple regression analysis showed no significant effect of cesarean section, birth weight and bathing on the time to umbilical cord separation.

The average parental satisfaction score in the triple dye group was significantly lower than those in the alcohol and no antiseptic groups (Table 3).

Umbilical cultures were performed in 180 infants at the mean postnatal age and post discharge of 6.51 $\pm$ 1.37 and 4.11 $\pm$ 1.32 days, respectively. There was no difference in timing of umbilical cultures among groups.

Cultures were positive for bacteria in all specimens. One hundred and fifty (83.3%) specimens were positive for multiple organisms. Klebsiellae was the most common organism identified and followed by *E. coli*, Enterobacter and Staphylococcus (Table 4). Staphylococcus was found in 54 (30.0%) specimens. All of them were coagulase- negative Staphylococcus. One specimen had both coagulase-negative and coagulase-positive Staphylococcus. The rates of

Table 3. Comparison of average satisfaction scores between triple dye and other groups

Group	n	Mean average scores	p-value*
Triple dye	63	3.72 (0.70)	0.019
Alcohol	60	4.04 (0.50)	
Triple dye	63	3.72 (0.70)	0.000
No antiseptic	62	4.22 (0.61)	

Mean scores presented as mean (standard deviation)
* Assessed by Mann-Whitney u test at significant p value < 0.025

Table 4. Distribution of organisms in positive umbilical cultures (n = 180)

Organisms	n	%
Klebsellae	108	60.0
E. coli	67	37.2
Enterobacter	57	31.7
Staphylococcus	54	30.0
Enterococcus	29	16.1
Acinetobacter	24	13.3
Pseudomonas	21	11.7
Proteus	16	8.9
Citrobacter	11	6.1
Streptococcus	6	3.3
Miscellaneous	7	3.9

Staphylococcal colonization in infants of triple dye, alcohol and no antiseptic groups were 25.4, 33.9 and 31.0%, respectively (p = 0.58) (Table 5). There was no difference in colonization rates of gram-negative organisms among groups.

During the study period, there were three infants having clinical sepsis. One infant from the triple dye group was admitted on the third day of life because of high temperature and irritability. One infant from the alcohol group was admitted because of abdominal distension and constipation at age of 3 weeks. The other from the alcohol group was diagnosed as urinary tract infection at the age of 3 weeks. No sign of umbilical inflammation was reported in all cases. The infections occurred after cord separation in 2 infants. They were treated with antibiotics for 3-5 days and blood cultures were negative in all of them.

Discussion

There has been many different umbilical cord care regimens described in previous studies. Although time to cord separation varied, most of them reported longer time to cord separation when triple dye was used compared to the regimens without triple dye[7-10]. The present study confirmed the effect of triple dye on delay of time to cord separation. Cesarean section was described to delay cord separation in previous studies possibly due to lack of inflammation process during delivery[9,12,13]. In the present study, the rate of cesarean section was significantly high in the triple dye group compared to other groups. The imbalance probably occurred by chance from the simple randomization and convenient sampling technique. However, the association of cesarean section to the time to cord separation was not demonstrated in the present study. Frequent bathing was another factor prolonged cord separation time in Bhalla's study[12]. Daily bathing in the present study also showed no effect on cord separation time.

Golombek[10] noted that parents expressed relief with cord separation in both the alcohol and triple dye groups. In Gladstone's study[8], parents were not satisfied with triple dye but the reason for dislike was not described. In the present study, the average scores in the triple dye was significantly lower than in other groups.

Almost all of umbilical cultures reported were performed at the time of hospital discharge ranging from 2-6 days of age[2-7,11,14-17]. Rate of colonization varied among studies. In the previous study, bacterial colonization rate of 100% was higher than in previous studies probably due to later timing of swab cultures. It was possible that the effect of antiseptic agents on preventing bacterial colonization decreased with time. The high rate of gram-negative bacteria without clinical infection was more likely from non-pathogenic organisms acquired from home environment. In the present study, there was no evidence of umbilical cord infection or definite sepsis. The association between umbilical cord colonization and risk of infection remained unclear. Home visits and intensive maternal education on umbilical cord care possibly played a role in preventing such infections.

In the present study, the authors demonstrated 2 alternative regimens of cord care at home, alcohol or no antiseptic agent, which shorten the time to cord separation and satisfying parents without evidence of umbilical cord infection. The authors

Table 5. Percentage of positive cultures for Staphylococcus

	Triple dye	Alcohol	No antiseptics	p-value*
Number of culture	63	59	58	0.58
Positive culture (%)	16 (25.4)	20 (33.9)	18 (31.0)	

* Assessed by Chi-square test

conclude that the regimen of umbilical cord care using triple dye in hospital following with alcohol or no antiseptic agent at home is safe and more favorable among a Thai population in Bangkok. Maternal education of clean cord care should be encouraged. Further studies in a larger population with a different setting is warranted.

References

1. World Health Organization. Care of the umbilical cord: a review the evidence [Online]. Available from:http://www.who.int/reproductive-health/publications/MSM 98 4/MSM 98 4 table of contents.en.html [2003,June,8].
2. Pildes RS, Ramamurthy RS, Vidyasagar D. Effect of triple dye on staphylococcal colonization in the newborn infant. J Pediatr 1973; 82: 987-90.
3. Speck WT, Driscoll JM, Polin RA, O'Neill J, Rosenkranz HS. Staphylococcal and streptococcal colonization of the newborn infant: effect of antiseptic cord care. Am J Dis Child 1977; 131: 1005-8.
4. Andrich MP, Golden SM. Umbilical cord care. A study of bacitracin ointment vs triple dye. Clin Pediatr (Phila) 1984; 23: 342-4.
5. Barrett FF, Mason EO Jr, Fleming D. Brief clinical and laboratory observations. J Pediatr 1979; 94: 796-800.
6. De Loache WR, Cantrell HF, Reubish GK. Prophylactic treatment of umbilical stump: comparison of technics. South Med J 1976; 69: 627-8.
7. Panyavudhikrai S, Danchaivijitr S, Vantanasiri C, Trakulsomboon S, Kolatat T, Dhiraputra C, et al. Antiseptics for preventing omphalitis. J Med Assoc Thai 2002; 85: 229-34.
8. Gladstone IM, Clapper L, Thorp JW, Wright DI. Randomized study of six umbilical cord care regimens. Comparing length of attachment, microbial control, and satisfaction. Clin Pediatr (Phila) 1988; 27: 127-9.
9. Hsu CF, Wang CC, Yuh YS, Chen YH, Chu ML. The effectiveness of single and multiple applications of triple dye on umbilical cord separation time. Eur J Pediatr 1999; 158: 144-6.
10. Golombek SG, Brill PE, Salice AL. Randomized trial of alcohol versus triple dye for umbilical cord care. Clin Pediatr (Phila) 2002; 41: 419-23.
11. Belfrage E, Enocksson E, Kalin M, Marland M. Comparative efficiency of chlorhexidine and ethanol in umbilical cord care. Scand J Infect Dis 1985; 17: 413-20.
12. Bhalla JN, Nafis N, Rohatgi P, Singh. Some observations on separation of the umbilical stump in the newborn. Indian J Pediatr 1975; 42: 329-34.
13. Novack AH, Mueller B, Ochs H. Umbilical cord separation in the normal newborn. Am J Dis Child 1988; 142: 220-3.
14. Wald ER, Snyder MJ, Gutberlet RL. Group B beta-hemolytic streptococcal colonization. Acquisition, persistence, and effect of umbilical cord treatment with triple dye. Am J Dis Child 1977; 131: 178-80.
15. Verber IG, Pagan FS. What cord care - If any? Arch Dis Child 1993; 68: 594-6.
16. Janssen PA, Selwood BL, Dobson SR, Peacock D, Thiessen PN. To dye or not to dye: a randomized, clinical trial of a triple dye/alcohol regime versus dry cord care. Pediatrics 2003; 111: 15-20.
17. Meberg A, Schoyen R. Bacterial colonization and neonatal infections. Effects of skin and umbilical disinfection in the nursery. Acta Paediatr Scand 1985; 74: 366-71.

การศึกษาวิธีการเช็ดสะดือที่บ้าน 3 วิธี ในทารก เพื่อเปรียบเทียบระยะเวลาการหลุดของสายสะดือ ความพึงพอใจของบิดามารดา และการตรวจพบเชื้อที่สะดือ

แสงแข ชำนาญวนกิจ, เกศนี เดชาราชกุล, พรพัฒน์ รัศมีมารีย์, นิรันดร์ วรรณประภา

วัตถุประสงค์: *เพื่อศึกษาระยะเวลาการหลุดของสายสะดือและความพึงพอใจของบิดามารดา เปรียบเทียบระหว่างการเช็ดสะดือที่บ้าน ด้วยทริปเปิลดายส์ แอลกอฮอล์ และไม่ใช้สารป้องกันการติดเชื้อใด ๆ*

วัสดุและวิธีการ: *ทารกจะได้รับการสุ่มเข้ากลุ่มตามชนิดของสารที่ใช้เช็ดสะดือที่บ้าน กลุ่มที่ 1) ทริปเปิลดายส์ กลุ่มที่ 2) แอลกอฮอล์ หรือ กลุ่มที่ 3) เช็ดสะดือให้แห้งโดยไม่ใช้สารป้องกันการติดเชื้อ ทารกจะได้รับการเพาะเชื้อที่สะดือเมื่ออายุประมาณ 1 สัปดาห์, เมื่อทารกอายุ 1 เดือน ผู้วิจัยจะสอบถามบิดามารดาถึงระยะเวลาที่สายสะดือหลุดและความ พึงพอใจ*

ผลการศึกษา: *ทารกในแต่ละกลุ่ม มีจำนวน 63, 60 และ 62 ราย ตามลำดับ ระยะเวลาที่สายสะดือหลุดในทารกกลุ่มที่ 1 จะนานกว่ากลุ่มที่ 2 ($p = 0.036$) และกลุ่มที่ 3 ($p = 0.003$) คะแนนความพึงพอใจของบิดามารดาในทารกกลุ่มที่ 1 จะต่ำกว่า ในกลุ่มที่ 2 ($p = 0.019$) และกลุ่มที่ 3 ($p < 0.01$) ผลการเพาะเชื้อที่สะดือจำนวน 180 ราย พบเชื้อแบคทีเรียทุกราย แต่ไม่พบ ภาวะสะดืออักเสบ*

สรุป: *ระยะเวลาที่สายสะดือหลุดเมื่อเช็ดสะดือที่บ้านด้วยแอลกอฮอล์หรือไม่ใช้สารป้องกันการติดเชื้อ สั้นกว่าและเป็นที่ยอมรับมากกว่าการเช็ดด้วยทริปเปิลดายส์ การเช็ดสะดือด้วยแอลกอฮอล์หรือการเช็ดสะดือให้แห้งโดยไม่ใช้สารป้องกันการติดเชื้อ จึงเป็นอีกทางเลือกหนึ่งของการดูแลสะดือทารกที่บ้าน*