

CHAPTER 4

RESULTS OF THE STUDY

4.1 Characteristics of the study samples

During the study period, there were 734 infants born in Phramongkutklao Hospital. 694 infants were admitted in the newborn nursery. Umbilical infection was diagnosed in two of them on the second days 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 study. The means of maternal age, gestational age, birth weight and length of hospital stay were not different among groups. There was no difference in the percentages of primiparous mothers and male infants among groups. Most of infants were fed with breast milk with or without formula milk and were daily bathed at the time of home visits. No difference in the percentages of breast feeding and bathing among groups. However, the rate of cesarean section was higher in the triple dye group compared to in other groups (Table 4.1).

Home visits within 1 week after discharge from hospital were conducted to monitor maternal compliance and to perform umbilical swab cultures. Deviations from the study protocols were noted in 4 infants (Table 4.2). Reasons for these deviations were erroneous antiseptic agents provided from hospital (1 in triple dye and 1 in alcohol group), misunderstanding of the protocol (1 in triple dye group) and maternal concern of delayed cord separation (1 in no antiseptic group). No other antiseptic agent outside of the protocol was used before cord separation. After cord separation, antiseptic powder or solution was applied on umbilicus in 3 infants due to maternal concern of exudative discharge. At one month of age, infants were followed-up at a pediatric outpatient clinic. The records of time to cord separation, parental satisfaction scores and adverse outcome were 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.

Table 4.1 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 4.2 Deviations of umbilical cord care at home

| Group | n | No of cases | Deviation of cord care |
|----------------|----|-------------|--|
| Triple dye | 63 | 2 | - Alcohol 2 day and then triple dye 13 days - Triple dye 7 days and then dry cord care 7 days |
| Alcohol | 60 | 1 | - Triple dye 2 days and then alcohol 7 days |
| No antiseptics | 62 | 1 | - Dry cord care 8 days and then triple dye 2 days |

4.2 Time to umbilical cord separation

Time to cord separation ranged from 3.71 to 34.81 days (Table 4.3). 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 4.3). Since the samples came from normally distributed populations, one-way ANOVA was performed and revealed a significant difference in the mean time to cord separation among groups ($p = 0.001$). Because equal variance was not assumed, post-hoc comparisons were performed by using Dunnett T3. The analysis showed significant differences in the time to umbilical cord separation between triple dye and other groups. The mean differences of triple dye group compared to alcohol and to no antiseptic group were 2.46 (95%CI 0.12 to 4.80) and 3.14 (95%CI 0.88 to 5.39), respectively (Table 4.4). There was no difference between alcohol and no antiseptic groups

Table 4.3 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 assessed by ANOVA, $p = 0.001$

Table 4.4 Mean difference of time to cord separation (day) compared between groups

| Group comparison | Mean difference | 95% CI | | P* |
|------------------------------|-----------------|-------------|-------------|-------|
| | | Upper bound | Lower bound | |
| Triple dye vs Alcohol | 2.46 | 0.12 | 4.80 | 0.036 |
| Triple dye vs No antiseptics | 3.14 | 0.88 | 5.39 | 0.003 |
| Alcohol vs No antiseptics | 0.67 | -1.10 | 2.45 | 0.735 |

* Assessed by Dunnett T3

Adjusting for covariates

Multiple regression analysis showed no significant effect of explanatory variables or covariates on the time to umbilical cord separation (Table 4.5)

Table 4.5 The effect of covariates on time to cord separation

| Variables | Unstandardized coefficient (β) | Standard error | Standardized coefficient (β) | t | p |
|------------------|--|-------------------|--|--------|-------|
| Intercept | 14.697 | 3.773 | - | 3.896 | 0.000 |
| Cesarean section | 0.856 | 1.225 | 0.052 | 0.699 | 0.486 |
| Birth weight | 0.00017 | 0.001 | 0.011 | 0.147 | 0.883 |
| Bathing | -1.000 | 1.428 | -0.052 | -0.700 | 0.485 |

Adjusted R square = -0.011

4.3 Parental satisfaction

Non-parametric, Kruskal-Wallis test was used to assess the differences in parental satisfaction scores among groups. Mann-Whitney test identified the differences between 2 independent groups by adjusting the statistical significance at p value < 0.025.

There was a significant difference in average satisfaction score and in all items except for convenience item among groups (Table 4.6).

The comparison between triple dye and alcohol group showed that triple dye group had significantly lower scores in color item and in the average score (Table 4.7).

The comparison between triple dye and no antiseptic group also showed lower scores in the triple dye group for all items except for convenient score (Table 4.8)

Table 4.6 Mean satisfaction scores of each item

| Items | Triple dye n = 63 | Alcohol n = 60 | No antiseptics n = 62 | P* |
|----------------------------|----------------------|-------------------|--------------------------|-------|
| 1. Color | 3.44 ± 1.06 | 4.02 ± 0.75 | 4.13 ± 0.78 | 0.000 |
| 2. Odor | 3.62 ± 0.81 | 3.88 ± 0.87 | 4.02 ± 0.98 | 0.008 |
| 3. Dryness | 3.79 ± 1.14 | 4.07 ± 0.84 | 4.40 ± 0.82 | 0.001 |
| 4. Convenience | 4.13 ± 0.81 | 4.30 ± 0.59 | 4.34 ± 0.70 | 0.328 |
| 5. Time to cord separation | 3.63 ± 1.13 | 3.92 ± 1.00 | 4.21 ± 0.89 | 0.004 |
| 6. Average score | 3.72 ± 0.70 | 4.04 ± 0.50 | 4.22 ± 0.61 | 0.000 |

* Assessed by Kruskal-Wallis test

Average score is calculated from the total scores of all items divided by 5

Table 4.7 Comparison of each item between triple dye and alcohol groups

| Item | Group | n | Mean scores | p |
|-------------------------|------------|----|-------------|--------|
| Color | Triple dye | 63 | 3.44 (1.06) | 0.002* |
| | Alcohol | 60 | 4.02 (0.75) | |
| Odor | Triple dye | 63 | 3.62 (0.81) | 0.031 |
| | Alcohol | 60 | 3.88 (0.87) | |
| Dryness | Triple dye | 63 | 3.79 (1.14) | 0.282 |
| | Alcohol | 60 | 4.07 (0.84) | |
| Convenience | Triple dye | 63 | 4.13 (0.81) | 0.370 |
| | Alcohol | 60 | 4.30 (0.59) | |
| Time to cord separation | Triple dye | 63 | 3.63 (1.13) | 0.126 |
| | Alcohol | 60 | 3.92 (1.00) | |
| Average score | Triple dye | 63 | 3.72 (0.70) | 0.019* |
| | Alcohol | 60 | 4.04 (0.50) | |

Mean scores presented as mean (standard deviation)

* Assessed by Mann-Whitney test at significant p value < 0.025

Table 4.8 Comparison of each item between triple dye and no antiseptic groups

| Item | Group | n | Mean scores | p |
|-------------------------|---------------|----|-------------|--------|
| Color | Triple dye | 63 | 3.44 (1.06) | 0.000* |
| | No antiseptic | 62 | 4.13 (0.78) | |
| Odor | Triple dye | 63 | 3.62 (0.81) | 0.003* |
| | No antiseptic | 62 | 4.02 (0.98) | |
| Dryness | Triple dye | 63 | 3.79 (1.14) | 0.001* |
| | No antiseptic | 62 | 4.40 (0.82) | |
| Convenience | Triple dye | 63 | 4.13 (0.81) | 0.148 |
| | No antiseptic | 62 | 4.34 (0.70) | |
| Time to cord separation | Triple dye | 63 | 3.63 (1.13) | 0.001* |
| | No antiseptic | 62 | 4.21 (0.89) | |
| Average score | 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 test at significant p value < 0.025

4.4 Umbilical culture

Umbilical cultures were performed in 180 (97.30%) infants at the mean postnatal age and post discharge age of 6.51 ± 1.37 and 4.11 ± 1.32 days, respectively. There was no difference in timing of umbilical cultures among groups (Table 4.9).

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 4.10). Staphylococcus was found in 54 (30.0%) specimens. All of them were coagulase- negative staphylococcus. One specimen grew both coagulase-negative and coagulase-positive bacteria. The power was too low to detect the differences of staphylococcal or gram-negative bacteria colonization among groups (Table 4.11).

Table 4.9 Timing of umbilical swab cultures (day)

| | Triple dye n = 63 | Alcohol n = 59 | No antiseptics n = 58 | P* |
|--|----------------------|-------------------|--------------------------|------|
| 1. Age of culture (d) | 6.59 (1.42) | 6.71 (1.34) | 6.21 (1.31) | 0.12 |
| 2. Duration between discharge to culture (d) | 4.14 (1.41) | 4.20 (1.29) | 4.00 (1.25) | 0.64 |

Data presented as mean (standard deviation)

* Assessed by ANOVA

Table 4.10 Distribution of organisms in positive umbilical cultures

| 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 |

Table 4.11 Percentage of positive cultures for organisms

| | Triple dye n = 63 | Alcohol n = 59 | No antiseptics n = 58 | P |
|-----------------------------|----------------------|-------------------|--------------------------|-------|
| Staphylococcus (%) | 16 (25.4) | 20 (33.9) | 18 (31.0) | 0.579 |
| Gram negative bacteria* (%) | 52 (82.5) | 52 (88.1) | 51 (87.9) | 0.596 |

* Klebsiella, E. coli and Enterobacter

Assessed by Chi-square test

4.5 Adverse outcome

During the study period, there were three infants having clinical sepsis (Table 4.12). One infant was admitted on the same day of hospital discharge because of high temperature and irritability. One infant was admitted because of abdominal distension and constipation at age of 3 weeks. The other one was diagnosed as urinary tract infection at 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.

Three infants exhibited conjunctivitis, which was treated with local ophthalmic antibiotics. No omphalitis occurred in these infants.

Exudative discharge and bleeding during the time of cord separation were reported in 21 (11.4%) and 39 (21.1%) infants, respectively. There was no difference in the prevalence of exudative discharge and bleeding among groups (Table 4.13).

Umbilical granuloma occurred in one infant of triple dye group. He was successfully treated with silver nitrate at age of one month.

Table 4.12 Manifestation and age at presentation in infants suspected sepsis (n = 3)

| No | Group | Clinical manifestations | Age at presentation |
|----|------------|---------------------------------------|---------------------|
| 1 | Triple dye | High temperature and irritability | 3 days |
| 2 | Alcohol | Abdominal distension and constipation | 3 weeks |
| 3 | Alcohol | Fever (urinary tract infection) | 3 weeks |

Table 4.13 Maternal concerns and adverse outcome

| | Triple dye n = 63 | Alcohol n = 60 | No antiseptics n = 62 | P* |
|--------------------|----------------------|-------------------|--------------------------|------|
| Periumbilical area | | | | |
| Exudate (%) | 8 (12.7) | 8 (13.3) | 5 (8.1) | 0.60 |
| Bleeding (%) | 11 (17.5) | 15 (25.0) | 13 (21.0) | 0.59 |
| Conjunctivitis (%) | 0 | 2 (1.7) | 1 (1.6) | 0.36 |

* Assessed by Chi-Square or Fisher exact test