Original Articles

Safety of Neonatal Skin Cleansing in Rural Nepal

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Objective: *A high proportion of deaths during the neonatal period are attributed to infections. Neonatal skin plays an important role in protecting the newborn from invasive pathogens. In preparation for a study of newborn skin cleansing with chlorhexidine in Nepal, we evaluated the feasibility, acceptability, and safety of the newborn cleansing procedure.* ***Study Design/Setting:*** *Observational pilot study of full-body cleansing of newborns in rural Nepal.* ***Methods:*** *Thirty-two newborn infants were wiped with commercially available non-antiseptic baby wipes. Pre- and post-procedure axillary temperatures were recorded to estimate the impact of cleansing on body temperature. Skin aggravation, residual moisture, removal of vernix, and maternal satisfaction were assessed qualitatively.* ***Results:*** *Body temperature of newborns decreased an average of 0.40 °C (95% CI: 0.31–0.49 °C, p<0.0001) during the procedure. There was no evidence of skin aggravation, injury or removal of vernix, and mothers expressed satisfaction with the procedure. The procedure was simple and project workers were easily trained.* ***Conclusions:*** *Care must be taken to promptly wrap infants after skin cleansing procedures as slight temperature decrease was noted after the procedure. These pilot data indicate, however, that gentle cleansing of newborn skin poses minimal risk to infants. This procedure is safe and appropriate precautions can be taken to deliver safe skin antisepsis with chlorhexidine to infants in the community.*

Keywords: *Chlorhexidine, Neonatal infections, Skin antisepsis.*

OF the annual four million neonatal deaths, 99% occur in developing countries, and an estimated 36% are attributed to infections(1). In settings with high-mortality rates, the proportion due to infection is higher, estimated at 50%(2). There is an urgent need to identify affordable, acceptable, and efficacious interventions that may be implemented in both community and hospital settings to prevent these infections and substantially reduce mortality during the neonatal period(3,4). Recently, increased attention has focused on the important role of the skin in protecting newborn infants from invasive pathogens(5). In Egypt(6) and Bangladesh(7), topical treatment of preterm infants with emollients that enhanced skin barrier function was recently demonstrated to decrease the incidence of nosocomial infections by 40-55%. In a hospital-based

clinical trial in Malawi, a combination of maternal vaginal washing during labor, together with post-delivery whole body cleansing of newborns with 0.25% chlorhexidine reduced overall neonatal mortality by 22%(8). In Egypt, a similarly designed study of vaginal and neonatal skin cleansing with chlorhexidine demonstrated a 33% reduction in neonatal mortality(9).

Based on the strong safety record of chlorhexidine(10), the importance of skin barrier function in newborns, and the potential impact of chlorhexidine cleansing of newborn skin as an intervention to reduce neonatal mortality risk(8,9), we conducted a cluster-randomized, community-based trial of the impact of skin cleansing with 0.25% chlorhexidine on neonatal mortality in southern Nepal. Among low birth weight infants, the risk of neonatal mortality was reduced 28% for infants receiving wipes with chlorhexidine compared to placebo(11).

These studies provide compelling evidence that cleansing of newborn infants immediately after birth with a chlorhexidine solution can markedly reduce mortality risk. Given the significant public health impact of this intervention and potential implementation on a wide scale, safety aspects of the intervention require full discussion. While the World Health Organization (WHO) recommends that bathing after birth be postponed for at least 6 hours if not 2 to 3 days(12), the skin cleansing procedure implemented in the Nepal study involved the wiping of newborn skin with a moist towel as soon as possible after birth. Therefore, prior to implementing our large community-based trial, we conducted a pilot study to evaluate the safety of the skin cleansing procedure using non-antiseptic, commercially available baby wipes. Safety measures included pre- and post-procedure body temperature to evaluate heat loss; and qualitative descriptions of residual moisture and vernix, skin aggravation, and maternal satisfaction.

Subjects and Methods

The pilot study was conducted in Sarlahi district within the 30 Village Development Committees (VDC) in the surveillance area of the Nepal Nutrition Intervention Project, Sarlahi (NNIPS). Local resident female workers (WD) are employed by this project to monitor the population (50-100 households per WD) for vital events, including pregnancies and births.

One WD from each VDC was trained in the wiping procedure using life-size dolls for demonstration. A pre-determined systematic wiping procedure requiring the use of five baby-wipes (Pampers Wipesters(tm), Proctor & Gamble, Cincinnati, Ohio, USA) to cover the entire body, excluding face and ears, was followed. Workers were trained to conduct the wiping procedure in a gentle manner that minimized exposure and avoided skin irritation or removal of vernix from the newborn skin. The 160 pilot study wipes were divided into 32 zip-lock bags each containing five wipes.

Upon receiving notification of the birth of an eligible newborn, senior area coordinator (AC) went together with the trained WD from that VDC to conduct the pilot procedure. Immediately before and after the wiping procedure, the newborn's axillary temperature was measured using a digital thermometer. Post-procedure skin moisture was estimated by the AC using a 3-category scale: (1) not visibly moist after cleansing; (2) no drops on the skin, but visibly moist; or (3) drops seen on the skin. The skin was also assessed for signs of irritation. A brief questionnaire/checklist, including assessment of maternal satisfaction, was completed by the AC at each of the

cleansings. One of the authors (LM) directly observed 8 (25%) infant cleansings, and confirmed the assessments of skin moisture. Among these infants, degree of vernix removal during the procedure was also assessed and categorized qualitatively as: (1) none, (2) minimal, (3) moderate, (4) nearly all, or (5) too little pre-procedure vernix present to assess.

The sample size (n = 32) was sufficient to detect a difference between pre/post axillary temperature of 0.5ºF, assuming a correlation coefficient of 0.75 for the two measures, and a standard deviation of 1.2ºF. At the field site, all temperature readings were recorded on the Fahrenheit scale and converted to Celsius for analysis. Differences in temperature measurements were estimated using a paired *t*-test, while other outcomes were examined by simple tabulation. All mothers who were approached agreed to participate and provided informed consent. The study procedures were approved by the Committee on Human Research at The Johns Hopkins Bloomberg School of Public Health and the Nepal Health Research Council.

Results

The pilot cleansing procedure was conducted during a one-week period in April 2002. The average daily maximum and minimum outdoor temperatures during this period were 33.7ºC and 20.5ºC, respectively. Thirty-two consecutive newborn infants (mean age 23.8 hours, range: 3-74 hours) from 18 VDCs, representing both major ethnic groups (Pahadi, Madeshi) in the community, were enrolled.

The average time required for the cleansing procedure was 5 minutes. After the procedure, no babies had visible drops of fluid on the skin, while for 6/32 (19%) the skin was visibly moist but no drops were present, and for 26/32 (81%) the skin was barely wet, or not visibly moist after cleansing (*Table I*). There was full agreement between the AC and LM in the skin

TABLE I–*Skin Moisture, Axillary Temperature and Hypothermia Status of Newborns Before and After Cleansing with Non-antiseptic Baby Wipes.*

	Before cleansing	After cleansing
Skin Moisture Assessment (#)		
Not visibly moist	32	26
Visibly moist / no drops	0	6
Visibly moist with droplets	0	0
Temperature (°C*)*		
Mean (SD)	36.5 (0.7)	36.1 (0.8)
Range	33.5 - 37.7	33.1 - 37.2
*Hypothermia*Status* (#)		
Normal	19	11
Mild	9	10
Moderate	4	10
Severe	0	0

*Normal >=36.5ºC; Mild (35.9 ºC-36.5 ºC); Moderate (32.0 ºC-35.9 ºC); Severe <32.0 ºC

moisture rankings in each of the 8 directly observed cases. Among 5 of these observed cases, there was a slight reddening of the skin that dissipated within minutes. Among two of the infants observed by LM, the amount of vernix removed during the procedure was minimal, while for the remaining 6 there was no visible vernix remaining after the traditional bath given by the family and before the study wiping procedure was conducted.

In 30 of 32 cases, the temperature after the procedure was lower than that before (range: -0.9 to + 0.1ºC change). Mean axillary temperature, standard deviation, range, and hypothermia status of infants before and after the procedure are shown in the *Table I.* The mean decrease in body temperature was 0.40ºC (95% CI : 0.31-0.49ºC). Among 19 babies with initial temperatures in the normal (≥ 36.5ºC) range, 8 (42%) became mildly hypothermic after the procedure. Among nine infants with a mild degree of hypothermia (35.9-36.5ºC) at baseline, 6 (67%) had temperature readings in the moderately hypothermic range (32.0-35.9°C) after cleansing. No pre/post temperature readings spanned two hypothermia categories. There was no indication of a trend towards greater temperature changes among newborns cleansed closer to the time of birth. Similarly, the change in body temperature was not related to the temperature recorded before the procedure.

In each case, all five wipes were used by the WD in the order instructed. The procedure for wiping the child was easily explained to both WD and mother. All mothers indicated that they were happy with the procedure and had no safety concerns.

Discussion

There was no evidence that the procedure caused any injury to or, significant removal of vernix from the skin, and any associated skin aggravation (*i.e.,* redness) was transient. The lower temperature readings after the procedure, however, indicate that newborns cleansed in this manner are likely to lose heat through conduction and evaporation. The mean change in temperature (0.4ºC) was comparable to temperature loss recently reported among tub-bathed (0.2ºC) and sponge-bathed (0.4ºC) infants in a Canadian hospital-based study(13). Anderson(14) reported a mean temperature loss of 0.1 ºC among 20 infants bathed in a deep-water bath, while Medves(15) estimated a mean temperature decrease of 1.2ºC and 1.5ºC among 111 infants washed by mothers and nurses, respectively. In another study, among 80 newborns bathed within 2 hours of birth, the decrease in temperature ranged from 0.1 to 1.0ºC(16). Thus, although the skin cleansing procedure is unlike a submersion or sponge bath, the risk for loss of body heat appears to be on the order of or less than that encountered during these bathing procedures.

Hypothermia in the newborn increases risk of illness and death, and is related to gestational age and weight at birth(12). In this pilot study, infant weight was not recorded, precluding an examination of body temperature change stratified by infant weight. The mean time between birth and cleansing was almost 24 hrs in this pilot study, and age at the time of the procedure was not associated with body temperature change. During the main trial of impact of chlorhexidine cleansing, however, the average time to cleansing was significantly closer to the time of birth (approximately 6 hrs), as WDs provided the intervention directly upon learning of the birth, and did not wait for AC supervision to apply the treatment. Others have examined axillary temperature and temperature loss within the first six hrs after birth, finding little evidence for an association between age and temperature loss after bathing

during these initial hours after birth(16,17). While the time of day when the procedure was conducted may have impacted the changes in temperature, we did not attempt to standardize this aspect of the procedure as the subsequent large trial of antiseptic cleansing aimed to deliver the intervention as soon as possible after birth without regard to time.

Although the body temperature loss recorded here was low and comparable to or less than reductions seen among newborns undergoing routine care in developed country hospital settings, the potential drop in temperature during the procedure does warrant increased emphasis and attention during training. All trainees should be given adequate messages concerning hypothermia risk. Moreover, the entire temperature decrease should not be attributed to the cleansing procedure alone, as infants are also likely to lose heat while the swaddling clothes are removed. Therefore, the importance of prompt and consistent wrapping of the newborn, kangaroo-mother care, or extra swaddling as appropriate to the culture, should also be emphasized. In periods or settings where the ambient temperature is lower than encountered during this study in April in Nepal, further emphasis on hypothermia prevention may be warranted.

Despite WHO recommendations for delayed bathing of newborns for at least 6 hrs after birth(12), previous research in the study area showed that 95% of families conduct a wet wash of the newborn within the first 12 hours after delivery(18). This routine practice in the community, combined with rigorous massage of newborns with mustard seed oil(18), may result in rapid removal of much of the vernix. Among the infants assessed for removal of vernix during the procedure, many did not have sufficient vernix remaining after the traditional bath by the family that typically was given before the baby was reached by study personnel. Among the infants who did have residual vernix after the traditional bath, there was no evidence of further removal of vernix during the study procedure. Thus, while it is important to emphasize gentle contact with the skin during skin wiping, and thus to avoid vernix removal or skin irritation, further research is needed on effective ways to promote delayed bathing and appropriate methods of skin cleansing of newborns by families(19).

Data collected during this pilot study aided in the design of the final protocol for wiping newborns in the community. For example, given the small amount of moisture present on the skin after the procedure and the residual antimicrobial effect of chlorhexidine(20), we decided to allow any moisture on the skin to remain after the wiping procedure, thus also avoiding any further wiping/rubbing process that might aggravate the skin or remove vernix. During training of our field workers, we emphasized the importance of completing the wiping procedure as quickly and gently as possibly, and promptly wrapping the child after the last wipe was used. We also provided all WDs with a bar of soap to be used for hand-washing before conducting the cleansing procedure. While the five wipes were sufficient in this pilot study for cleansing the infants, for the main trial we included a sixth wipe in the package in the event that one of the wipes became soiled.

Community health workers can be trained to conduct full-body cleansing of newborns in a simple and acceptable manner. If a safe and effective broad-spectrum antiseptic solution were readily available, this procedure represents an acceptable method for delivering that antiseptic to newborns in the community. A leading candidate is chlorhexidine, which has been used extensively as a topical and surgical antiseptic for the past five decades and has a strong safety record(10). Studies of full-body

Key Messages

- Cleansing of newborns with chlorhexidine has significant potential for reducing neonatal mortality risk, but safety issues related to the cleansing procedure must be reviewed.
- In this pilot study, pre/post body temperature decrease was low (0.4 ºC) and comparable to or less than seen during routine bathing of newborns in neonatal nurseries.
- Newborn skin cleansing can be conducted in the community with minimal or no risk to infants.

cleansing of neonates have shown minimal to no percutaneous absorption through the skin(21-24), and no indication that any trace absorption has negative effects. In hospital-based studies in Malawi(8) and Egypt(9), respectively, 3743 and 2295 babies were wiped with a cloth soaked in 0.25% chlorhexidine solution immediately after birth with no reported adverse events.

Conclusion

These pilot study data indicate that full-body cleansing of neonates can be conducted in the community with minimal or no risk to infants. A slight decrease in body temperature during the procedure could be minimized with protective measures and educational messages. The minimal risks highlighted in this pilot study or those associated with chlorhexidine must be considered in a balanced way with the potentially significant positive impact of full-body or umbilical cord cleansing with chlorhexidine on neonatal infections and death. In the hospital-based studies in Malawi and Egypt, neonatal mortality was reduced in the chlorhexidine group by 22% and 33%, respectively(8,9), while mortality among low birth weight infants was reduced by 28% in the Nepal community-based study(11).

Skin cleansing in the community represents a safe, simple, affordable, and potentially easily-implemented intervention to reduce neonatal mortality. Further investiga-tions of the optimal concentration of chlorhexidine solution and identification of the most effective community-based delivery methods for chlorhexidine cleansing of newborns is warranted.

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