

Tolerance of Baby Cleansers in Infants: A Randomized Controlled Trial

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This randomized controlled trial was conducted to evaluate the tolerability of a new baby cleanser formulation - Johnson's Top-to-Toe cleanser (JTT) on infantile skin. 180 healthy infants (60 in each group) were enrolled and JTT Sebamed Baby Liquid cleanser (SM), and lukewarm tap water were used on the skin of the subjects as whole body cleansers twice a week for 2 weeks. Assessment was done at baseline, 1 week and 2 weeks clinically by a dermato-logist, instrumentally, and by the parents. Clinical assessment (erythema, edema, dryness and scaling); skin moisture content; skin surface pH; trans-epidermal water loss; skin oxyhemoglobin and deoxyhemoglobin; and consu-mer satisfaction were the outcome measures. There was no significant erythema, edema, dryness, or scaling elicited by any of the three test components. Parents did not report any side-effects. All the three studied interventions used as whole body cleansers were efficacious and well tolerated by infants.

Key words: *Baby cleanser, Infant, Moisture, Tolerability, Epidermal water loss, Skin.*

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The neonatal skin is more prone to damage from environmental agents as opposed to adult skin due to epidermis being loosely bound to the dermis, the skin being thinner and less elastic, less developed epidermal barrier, and lesser melanin content(1). Using a proper cleanser for bathing neonatal and infantile skin is of prime importance considering the anatomical differences from adult skin, which make it more prone to sensitivity to cleansers.

An important developmental variation of the infant skin is the "acid mantle" or the functioned capacity of the skin to form a surface pH of less than 5. There is a close relationship between the skin surface pH and its microbial flora(2). An increase in skin pH from acidic to neutral can cause an increase in the total number of bacteria and a shift in the

species present(3); hence, it is important to maintain this acid mantle on baby skin. Most soaps have an alkaline pH and can alter the acid mantle of the skin when used for cleansing baby skin(4). Syndets or synthetic detergents are non-soap surfactants which have a pH closer to normal skin, a decreased irritancy potential, lack of sensitization and capability to maintain or even restore the acid mantle of the skin as well as maintaining the "barrier function" of the skin(5). The present study was undertaken to evaluate the tolerability of a new baby cleanser formulation Johnson's Top-to-Toe cleanser as compared to a standard market formulation and normal water as controls on infantile skin.

METHODS

A controlled, parallel, randomized, stratified (by age

using a randomization software) study was carried out on 180 Filipino infants (age 1 day to <1 year). The baseline characteristics of the three groups are given in **Table I**. The net baseline characteristics were similar for all groups. These infants were in good health and had a normal skin. Prematurely born infants and those with congenital problems were excluded. An ethical clearance was obtained from the Institutional Research Board and written informed consent was taken from the parents.

The test products used were Johnson's Baby Top-to-Toe Wash (JTT) (Group I), Sebamed Baby Liquid cleanser (SM) and lukewarm tap water (Group III). These products were used on the skin of the subjects as whole body cleansers at least twice a week for 2 weeks. Assessment was done at baseline, and after 1 week and 2 weeks of use: (i) clinically by a dermatologist, (ii) instrumentally, and (iii) by the consumer (parent of the participant).

Clinical assessment: A dermatologist evaluated the infant for erythema, edema, dryness and scaling in four areas: head, upper limbs, body, lower limbs. A 5 point rating scale was used, where 0 indicated absence of symptoms and 5 indicated the most severe symptoms. The percentage area affected in each of the four body areas was also evaluated using the following scale: 0 = 0%, 1 = 1-9%, 2 = 10-29%, 3 = 30-49%, 4 = 50-69%, 5 = 70-89%, 6 = 70-100%.

Instrumental assessment: All subjects were evaluated for skin moisture content by conductance (Skicon 200, IBS Company, Japan); skin surface pH (Skin pH Meter, C and K, Germany); transepidermal water loss by measurement of relative humidity build-up inside a closed chamber (Vapometer, Delfin Technologies,

Finland); and apparent concentrations of skin chromophores, namely: oxyhemoglobin which relates to erythema, and deoxyhemoglobin which corresponds to vascular stasis, by diffuse reflectance spectroscopy (Ocean Optics, USA). Viscoscan (C & K, Germany) was used for image capture.

Consumer assessment: Parents were given a diary to note down comments or any observations and reactions with the use of the test product daily. A questionnaire was also administered to the parents/guardians after 1 and 2 weeks to check for consumer perception of the efficacy and side-effect (irritation) of the product.

All evaluations in the test center were performed in a climate-controlled facility with a temperature of 20-24⁰ C and a relative humidity of 40-60%. Subjects and their parents/guardians were asked not to apply the product prior to evaluation and to arrive 30 minutes before the evaluation to enable the subjects to adjust to the conditions.

Statistical analysis: Means were compared by analysis of variance (ANOVA) on related samples test (Friedman Wilcoxon) was done to check for significance between baseline and succeeding time points. $P \leq 0.05$ was taken as significant.

RESULTS

On clinical evaluation, there was no significant erythema, edema, dryness, or scaling elicited by any of the three tested compounds JTT, Sebamed liquid or lukewarm tap water, in any of the four regions (head, upper limbs, trunk and lower limbs) as compared to the baseline.

According to the instrumental assessment for moisture, both Group I and Group II treated subjects had significant increase in moisture level after 1 week of use but by the second week, moisture levels reverted to just above baseline levels (12% and 6% higher, respectively). Group I and III subjects had significant decrease in pH after 1 week of usage but the pH returned to baseline values by the second week. No changes in pH were noted in group II (**Table II**). SM elicited only a relative increase in trans-epidermal water loss (TEWL) at 2 weeks, however this appeared to be insignificant as the

TABLE I BASELINE CHARACTERISTICS OF THE STUDY POPULATION (EACH GROUP, $N=60$)

Groups	Age* (months)	Males	Age <6 months
JTT	5.45 (2.37)	38	32
SEBAMED	5.46 (2.32)	28	30
Water	5.44 (2.17)	28	31

* Values in mean (SD): JTT: Johnson's top-to-toe cleanser, SEBAMED: Sebamed baby liquid cleanser, SD: standard deviation.

TABLE II COMPARISON OF SKIN MOISTURE, SURFACE pH, TRANSEPIDERMAL WATER LOSS, OXYHEMOGLOBIN AND DEOXYHEMOGLOBIN, AFTER APPLICATION OF JOHNSON'S TOP-TO- TOE CLEANSER, SEBAMED BABY LIQUID CLEANSER AND WATER

Parameters	JTT (n=60)	SEBAMED (n=60)	Water only (n=60)
Moisture(microSiemens)			
baseline	26.6 ± 16	29.6 ± 21	33.0 ± 25
1 wk later	37.0 ± 26*	44.4 ± 40*	38.8 ± 30
2 wk later	29.8 ± 20	31.5 ± 17	34.7 ± 26
Skin pH			
baseline	4.89 ± 0.4	4.88 ± 0.3	4.85 ± 0.3
1 wk later	4.78 ± 0.2**	4.80 ± 0.3	4.75 ± 0.4**
2 wk later	4.83 ± 0.3	4.79 ± 0.3	4.79 ± 0.3
Transepidermal water loss (g/m ² hour)			
baseline	15.2 ± 4.5	14.5 ± 4.0	14.6 ± 5.4
1 wk later	15.4 ± 10.2	16.2 ± 9.6	16.1 ± 8.1*
2 wk later	16.3 ± 7.3	16.3 ± 5.9*	15.1 ± 6.1
Skin oxyhemoglobin (AU/Absorbance unit)			
baseline	0.189±0.157	0.165±0.131	0.143±0.135
1 wk later	0.191±0.145	0.190±0.134	0.177±0.133
2 wk later	0.199±0.107	0.185±0.101	0.202±0.102*
Skin deoxyhemoglobin (AU/Absorbance unit)			
baseline	0.600±0.210	0.568±0.233	0.548±0.247
1 wk later	0.683±0.238	0.672±0.219*	0.631±0.279
2 wk later	0.671±0.256	0.654±0.223	0.711±0.229*

JTT: Johnson's top-to-toe cleanser; SEBAMED: Sebamed baby liquid cleanser (SM); *Significantly higher than baseline at 95% confidence intervals; ** Significantly lower than baseline at 95% confidence intervals.

moisture content with SM was more than JTT at baseline and was comparable to baseline. No significant changes in TEWL were noted in group I group III, as compared to baseline values. Other results of instrumental assessment are shown in **Table II**.

On consumer self-assessment, all the attributes (skin is not dry/skin is not irritated/skin feels soft and smooth/skin is clean/skin is not red/ good for everyday cleaning/protects baby's sensitive skin) were graded as 4 or 5 which corresponded to either "agree" or "strongly agree", respectively to the stated attribute. No significant differences were noted when comparing all the products versus each other.

In group I, 1/60 subject had mild rashes and redness on the neck and arms that appeared around 4 days after use. The irritation appeared 2-3 hours after bathing and lasted for a few minutes. In group II, 2/60 subjects had irritation in the first week. These were mild rashes on the back and leg and lasted for 1-2 days. For group II, 1/60 subject had mild rashes and dryness 3 days after starting use of the product. No irritation was noted with any of the three compounds in the second week.

DISCUSSION

The skin of the neonate and infant is thought to be more sensitive than that of adults and differs in some characteristics(1,6,7). The skin's "barrier function"

WHAT IS ALREADY KNOWN ?

- Tolerance and safety of baby cleansers are of prime importance as the skin of infants is extremely sensitive to cleansers.

WHAT THIS STUDY ADDS?

- A new baby cleanser formulation (Johnson Baby Top to Toe) is well tolerated by infants, as also Sebamed and Lukewarm tap water.

mainly resides within the stratum corneum layer of the epidermis. It consists of the keratinocytes (constituting of proteins and lipids), embedded in a lipid rich matrix consisting of cholesterol, ceramides and fatty acids. Another class of lipids is also secreted at the surface of the epidermis, which when in contact with the environment interacts with water forming the hydrophilic film, which is important for the sensorial attributes of the skin. The lipid fraction of this hydrophilic film can also penetrate in the upper layers of the epidermis merging with the epidermal barrier and also contributing to its functions(8,9). The use of soaps or detergents (containing surfactants) can have a deleterious effect on the “barrier function” of the skin(10-13). Alkaline soaps and detergents also disturb the physiological “acid mantle”, changing the composition of the cutaneous bacterial flora and the activity of enzymes in the upper epidermis, which have an optimum acid pH(3). All this can result in skin dryness, roughness, flakiness and a tightening effect(10,11). Thus, choosing the cleanser for the skin of the newborn and infants to choose from the available classic soaps, liquid soaps, and soapless synthetic detergents or syndets, needs caution(4,5).

Cleansers containing soapless synthetic detergents with a neutral or a slightly acidic pH are practical alternative to soap for cleaning neonates and infants(4). They do not strip away the moisture protecting lipid film and do not alter the protective “acid mantle” as they have a pH closer to normal skin. Although there are several agents available in the Asian market, most do not mention their composition and do not have observable benefits for infants. There are few published Asian studies using instrumental methodologies to study the mildness of soaps and cleaners on the physiological parameters of infant skin(4,14). We studied safety and tolerance

of a new baby cleanser formulation that can be applied to the baby skin, rubbed to produce lather and then wiped dry with a soft cloth.

In the present study, no statistically significant irritation was visible to the clinician for all three groups of the study, showing that the new liquid cleanser formulation, a well established market product (a cleanser) and warm tap water, were mild on the baby skin. The moisture content in one group others at study initiation, and comparable with baseline. This was the drawback of the study. Further studies of a similar nature, with the cleansers being tested having comparable baseline values are required to draw firm conclusions.

Based on dermatological, instrumental and consumer self-assessment, there were no tolerance issues with any of the three compounds and hence all three can be considered safe for use in infants with normal skin.

Contributors: MDV conceived and designed the study and revised the manuscript. She will act as guarantor of the study; CG, RE, NM, RG collected the data and interpreted the laboratory tests and data and helped in drafting the manuscript; RS helped in manuscript writing and critically revised the manuscript for intellectual content. The final manuscript was approved by all authors.

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