

An open clinical study to evaluate dermal safety and post-application effect of a herbal Baby Lotion

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ABSTRACT

Present study was undertaken to evaluate the safety and efficacy of a novel herbal Baby Lotion. This study was carried out on 20 babies in the Dermatology of Dermatology, Apollo Hospital, Chennai, India. The duration of the study was 30 days. Results indicated that the Baby Lotion was well tolerated and significantly improved skin softness and smoothness. It also produced a significant moisturizing effect. Parents felt that the Baby Lotion produced excellent results on their babies. There was no adverse effect on application of the Baby Lotion over a period of one month.

INTRODUCTION

A baby's skin is extremely delicate and sensitive. Infantile dry skin (xerosis) is a common dermatological condition characterized by dry and rough skin.

Topical oil massage for babies is routinely practiced in many countries. For hundreds of years, populations especially in the Indian subcontinent have routinely applied natural oils to the skin of newborns. The practice of oil massage has gained favor in neonatal intensive care units in developed countries as well.¹

The putative benefits to the newborn are twofold, those related to the oil application per se, and those related to tactile kinesthetic stimulation due to the massage. Topical oil application has been shown to improve skin barrier function, thermoregulation and is suggested to have a positive effect on growth.^{2,3} A role for absorption of fats through the thin skin of the preterm has also been suggested. Moreover, a number of studies have also demonstrated superior growth and development in preterm infants receiving tactile kinesthetic stimulation.⁴⁻⁸ Oil application may occasionally cause adverse effects in the form of skin rashes and a greater propensity for bacterial colonization.¹ A number of herbs are claimed to have beneficial effect when used for massage in babies. They are claimed to be safer without any adverse effects.

A novel herbal Baby Lotion is now available for application in babies. Present study was planned to evaluate the safety and efficacy of this herbal Baby Lotion. Baby Lotion is a polyherbal formulation that consist of extracts of *Sida cordifolia*, *Glycyrrhiza glabra* and *Tinospora cordifolia*; and oil of *Olea europaea* and *Prunus amygdalus*.

SUBJECTS AND METHODS

This open clinical evaluation was conducted in the Department of Dermatology, Apollo Hospitals, Chennai, India, and was approved by the local ethical committee.

Inclusion criteria

Babies of either sex, aged between 6 months to 5 years, were included in the study provided they fulfilled the following criteria:

- a. Medically stable with no requirement of drugs (other than mineral or vitamin supplementation)
- b. Adequate family support
- c. Parents consenting to apply the Baby Lotion for the time required.

Exclusion criteria

- a. Exclusion criteria included sick babies, and those with congenital anomalies, neuromuscular problems and dermatological problems
- b. Application of any other baby oil/lotion.

Outcome variables

The primary outcome measure was to identify adverse reactions, if any, observed due to application of the Baby Lotion. Secondary outcome measures were to note down the post-application effects of Baby Lotion on skin softness, smoothness of the skin and moisturizing effect.

Baby Lotion Application

Parents of babies enrolled in the study were asked to apply Baby Lotion (Batch No. HDC/BL/40203) on the face and body once a day for a period of one month. The babies were examined initially, and on Day 15 and Day 30 of application of the Baby Lotion.

Assessment

At the initial visit, a detailed medical history was obtained by interviewing the parents regarding any dermatological problems observed so far in the baby.

During each medical visit, the babies were examined for any visible signs of erythema, pruritus, edema, and urticaria. Complaints of dry/oily skin were taken into account. The experience of parents of the babies during application of baby oil prior to this study was also taken into account. Post-application effect of Baby Lotion included parameters like skin softness, smoothness of skin and moisturizing effect. These parameters were scored as poor, fair, good, very good, and excellent.

Statistical analysis

Statistical analyses were carried out using Fisher's exact test to find out the level of significance. Analysis was carried out using GraphPad Prism software, version 4.01.

RESULT

Demographic data of the 20 babies who entered into the study are given in Table 1. All the included babies completed the study. None of the babies showed any adverse effects after the application of the Baby Lotion (Table 2). Effects of application of Baby Lotion on "after effects" were excellent. Skin softness was seen in all the

| Parameters | Number (n=20) |
|-------------------|----------------------|
| Male : Female | 7 : 13 |
| Age range | 6 months to 5 years |
| Median age | 144 days |

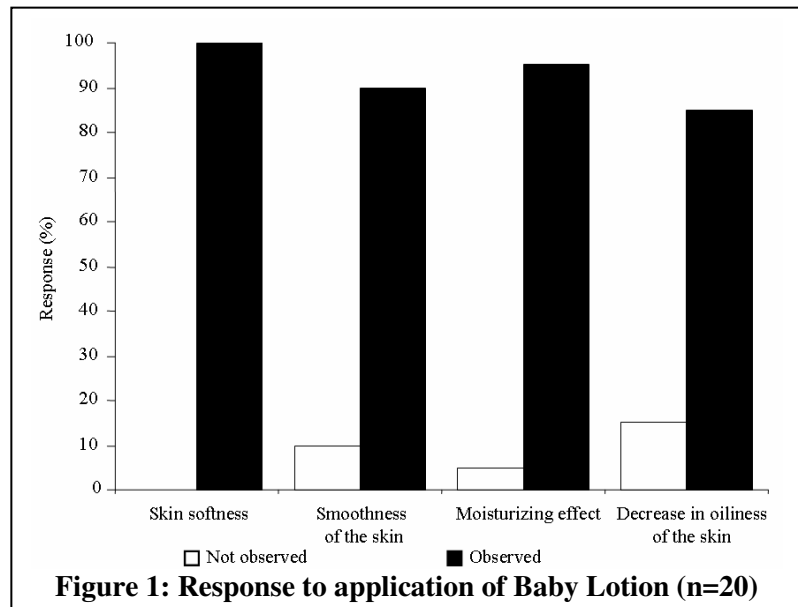
babies after the application of Baby Lotion. Skin smoothness and moisturizing effect was observed in 90% of the babies. All the parents were of the opinion that the application of Baby Lotion was highly beneficial (Table 3, and Figures 1 and 2).

| Signs and Symptoms | Days of application | | |
|------------------------|---------------------|-------------|-------------|
| | Initial | Week 1 | Week 2 |
| Erythema | 0.00 ± 0.00 | 0.00 ± 0.00 | 0.00 ± 0.00 |
| Edema | 0.00 ± 0.00 | 0.00 ± 0.00 | 0.00 ± 0.00 |
| Pruritus and Urticaria | 0.00 ± 0.00 | 0.00 ± 0.00 | 0.00 ± 0.00 |

| Parameter | Product Evaluation/Rating | Response (%) |
|----------------------------------|---------------------------|----------------|
| Skin softness | Observed | 100 (p<0.0001) |
| | Not observed | 0 |
| Smoothness of the skin | Observed | 90 (p<0.0001) |
| | Not observed | 10 |
| Moisturizing effect | Observed | 95 (p<0.0001) |
| | Not observed | 5 |
| Decrease in oiliness of the skin | Observed | 85 (p<0.0001) |
| | Not observed | 15 |
| Overall Impression | Very good to Excellent | 65 |
| | Good | 30 |
| | Fair | 5 |

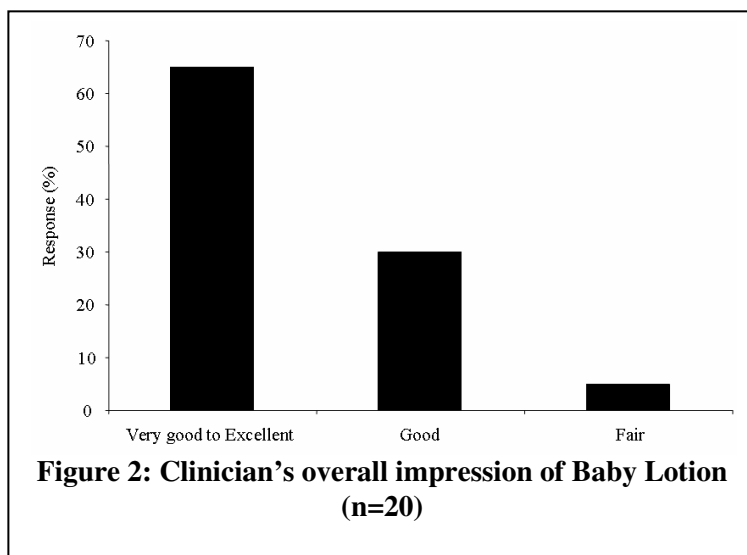
DISCUSSION

Irritation and sensitization potential of a cosmeceutical must be determined for local applicants. The test to determine the irritation and sensitization potential of a product are still at a initial stage of understanding. It is simply diagnosed by observing the skin over which the cosmeceutical has been applied. One needs to look at erythema, edema, pain and itching as a subjective sign of irritation and sensitization⁹.



From this study, it is evident that application of Baby Lotion has no adverse effects. When applied over a period of 30 days, it produced beneficial effects in the form of skin softness, smoothness and moisturizing effect. Overall result was very satisfying to the parents. They felt that the application of Baby Lotion was beneficial to their babies. None of the babies exhibited any adverse effect.

Beneficial effects seen with Baby Lotion cannot be attributed to single ingredients and appears to be due to the synergistic effect of all. *Sida cordifolia* has anti-inflammatory, and skin smoothening¹⁰ and vaso relaxation properties¹¹. *Glycyrrhiza glabra* has protective¹² and anti-inflammatory effects¹³. *Olea europaea* has a natural oil with good emollient effect. It also has antioxidant effect¹⁴ and antimicrobial property¹⁵. *Prunus amygdalus*, a vegetable oil, has emollient, moisturizing and antioxidant properties¹⁶.



It is possible that the beneficial effects observed in the study are due to the additive effect of all the ingredients. A further study with larger number of babies is recommended to know other beneficial effects of this novel herbal Baby Lotion.

CONCLUSION

Present study indicates the dermal safety and efficacy of novel herbal Baby Lotion. Application of this Baby Lotion is beneficial to the babies. Compliance to this lotion was satisfactory.

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