

Clinical study to evaluate dermal safety and after application feel of a novel Baby Cream: An open study

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ABSTRACT

An open clinical study was carried out to screen the efficacy and safety of a novel herbal Baby Cream. This study was carried out in the Department of Dermatology, Apollo Hospital, Chennai, India, on 20 babies. Parents of these babies were asked to apply the cream over the face and the body once a day for 4 weeks. These babies were examined prior to entry into the study and later at fortnightly interval. Adverse effects, if any, due to application of the cream were noted down. Efficacy of the cream was assessed on the basis of smoothness and softness of the skin and moisturizing effect.

Results indicated that the cream was highly efficacious and was very well tolerated. It did not lead to any adverse effects. It is concluded that the novel herbal Baby Cream is safe and efficacious.

INTRODUCTION

Skin is a unique organ in that it interfaces with the environment and shields the body from effects of irritants and pathogens. Vegetable oils are applied to make the skin function better.

Oil massage of newborn has been practiced for generations in the Indian sub-continent; however, oils may vary from potentially beneficial to potentially toxic¹. Topical application of natural oils is practiced routinely in many countries and may either improve skin barrier function and health, or have detrimental effects and systemic effects depending on the composition of the oil². Very little literature on epidemiology, practice and perceptions of traditional neonatal oil massage is available. Mustard oil massage may have detrimental effects, particularly in neonates, whose skin barrier function is otherwise suboptimal³. Trials on effect of massage on growth in preterm infants have used massage alone as a form of tactile stimulation or massage with same type of vegetable oil⁴.

Other natural oils such as sunflower, sesame or sunflower seed oil may have beneficial impact. Topical therapy to enhance skin barrier function may be simple, low cost and an effective strategy to improve clinical outcome.

A herbal Baby Cream is now available for local application to babies and children. Baby Cream is a polyherbal formulation that consists of extracts of *Sida cordifolia* and *Tinospora*

cordifolia, and oil of *Olea europaea*. Present study was undertaken to evaluate the safety and efficacy of Baby Cream in babies and children.

MATERIALS AND METHODS

Babies and children were enrolled into the study based on their clinical evaluation. The study was aimed at prospective evaluation of efficacy and safety of Baby Cream applied on the face and all over the body. This study was carried out in the Department of Dermatology, Apollo Hospitals, Chennai, India.

Parameters	Number (n=20)
Male : Female	8 : 12
Age range	6 months to 5 years
Median age	184 days

Children with the mean age of 184 days (Table 1) were enrolled in the study. Their parents were instructed to apply Baby Cream on the face and arms, once a day for a period of 4 weeks. No other local application was allowed.

Babies were excluded from the study if they had grown congenital anomalies or had any other clinically visible illness. Those with dermatological problems were also excluded from the study.

Primary outcome variable: Dermal safety.

Secondary outcome variable: Reduction in oiliness of facial skin, and soothing, smoothing and softening effect.

Data collection:

Baseline characteristics (Table 1) were obtained, including age, sex and illness, if any. After application of the Baby Cream, the babies were reviewed for 4 weeks. During this follow-up, they were examined for any change in skin appearance, oiliness and texture. Adverse events, if any, were noted.

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

A study was conducted to evaluate the dermal safety and post-application feel of Baby Cream in 20 children (8 male and 12 female). The mean age of the babies included in the study was 184 days. Parents were instructed to apply Baby Cream on the face and arms, once a day for a period of 4 weeks. The babies were reviewed at initial, 2, and 4 weeks post application to evaluate the dermal safety parameters, which included signs and symptoms such as erythema, edema, pain, pruritus and urticaria. Post-application effect of the product was evaluated using parameters like reduction in oiliness of the facial skin, soothing and smoothing effect, and softening effect. The dermal safety and after-application feel of the product is summarized in Tables 2 and 3.

Signs & 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
Pain	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 (%)
Reduction in oiliness of facial skin	Improvement	100 (p<0.0001)
	No improvement	0
Soothing and smoothing effect	Yes	100 (p<0.0001)
	No	0
Softening effect	Present	100 (p<0.0001)
	Absent	0
Overall Impression	Very Good	25
	Good	75
	Fair	0
	Poor	0

The Baby Cream application helped in reduction of oiliness of facial skin in all the babies. Similarly, it had a soothing and smoothing effect on the skin. Parents also reported that they found a remarkable softening effect on the skin of their babies.

It is observed that Baby Cream is completely safe with excellent compliance. Parents who were using other baby cream previously felt that this product was better than other baby creams.

DISCUSSION

This study was initiated to evaluate the efficacy and safety of a novel herbal Baby Cream. Results of this study indicate that herbal Baby Cream is very safe and efficacious in soothing and softening the skin of babies. Infantile skin is delicate and is at high risk of xerosis. Skin requires moisture to stay smooth and supple in order to perform its physiological function effectively. Skin participates in many of the

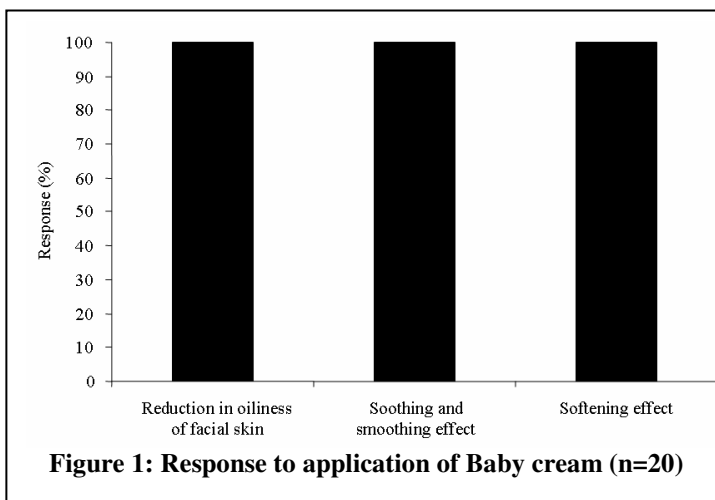


Figure 1: Response to application of Baby cream (n=20)

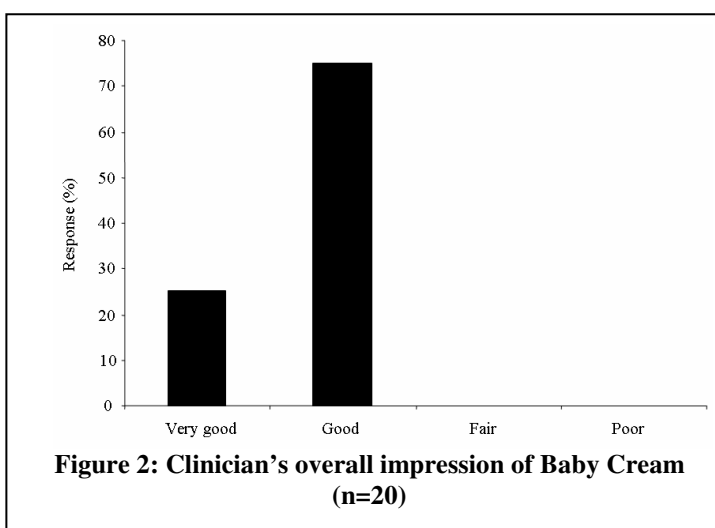


Figure 2: Clinician's overall impression of Baby Cream (n=20)

physiological and pathological events and processes. The cutaneous expression of internal disease is frequent, varied and often specific. Hence, skin needs to be protected and well preserved in babies. Cream application benefits babies as it stimulates all the senses of the baby and establishes a more intense visual and tactile communication. Massage by this cream aids growth and development. It also gives the mother the confidence in her ability to handle and comfort the baby. Various studies have documented anti-inflammatory and analgesic effects of *Sida cordifolia*^{5,6}, one of the ingredients of this herbal cream. *Glycyrrhiza glabra*⁷ and *Tinospora cordifolia* have skin nourishing effect⁸, and *Olea europea* has skin moisturizing and water holding effect^{9,10}. It is possible that the beneficial effects seen by this cream is an additive effect of all the ingredients.

CONCLUSION:

This study indicates that the novel herbal Baby Cream is safe and efficacious. It corrects common dermatological problems in babies and softens and soothes the skin. It has not produced any adverse effect.

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