

CLINICAL EVALUATION OF TWO BABY WIPES IN A CROSS-OVER STUDY.

Feliciani C*, Di Carlantonio M[§], Bellucci R[§], Guarracino M[§], and Amerio P.*

* Department of Dermatology, University "G.D'Annunzio", Chieti, Italy

§ Centro Ricerche Fater P&G SpA, Sambuceto, Italy.

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Synopsis

To investigate the safety of a new moisturized wipe we performed a double blind study evaluating several clinical and laboratory parameters. 55 babies, wearing diapers, (56% males, 44% females) were divided in two groups, both randomly stratified for age and sex. Age ranged from 1 month to 2 years. First group has been cleaned with a new baby wipe during the test phases and the second group with a commercially available baby wipe. Three visits have been made. During the calibration phase (between visit 1 and 2) the babies were cleaned with water and a uniform soap. During the test phase (between visit 2 and 3) the two baby wipes were exclusively used. At the beginning and at the end of the test phase a questionnaire for parents, a clinical evaluation of a dermatologist, skin pH measurement and skin microbiology were carried out. The use of the new baby wipe is safe and does not alter skin parameters compared to control product.

Riassunto

E' stato affrontato uno studio a doppio cieco per valutare, attraverso esami biologici e clinici, la sicurezza nell'uso di un nuovo detergente idratante.

55 bambini, affetti da eritema da pannolino (56% maschi e 44% femmine) sono stati suddivisi a doppio cieco in due gruppi, per età e sesso. L'età variava da 1 mese a 2 anni.

Mentre il primo gruppo è stato deterso con il nuovo fazzoletto detergente (durante la fase-test), il secondo gruppo veniva deterso con un fazzoletto detergente già in commercio.

Sono stati effettuati 3 controlli clinici.

Durante la fase di calibrazione (tra la 1 e la 2 visita) i bambini sono stati detersi in modo uniforme con acqua e sapone. Durante la fase-test (tra la 2 e la 3 visita) sono stati utilizzati soltanto i due tipi di fazzoletti detergenti.

All'inizio e alla fine della fase-test è stato realizzato un questionario per i genitori, una valutazione clinica da parte del dermatologo assieme ad un controllo del pH e della carica batterica cutanea.

L'uso del nuovo fazzoletto detergente è sicuro e non altera i parametri cutanei se paragonato al prodotto di controllo.

INTRODUCTION

The use of wipes is gradually increasing with modern habits that lead to the use of new products in baby toiletries.

Wipes are very practical tools in baby cleaning because of their thinness, moisture, small space they occupy, and their easy use. Wipes are designed to have the right moisture and a pleasant smell. Wipes must not be too wet so as to dilute the excrements or to leave the skin humid, neither too dry so as not to clean or to irritate the diaper area. It must be kept in mind that the wipes are used at every diaper change, more than a normal cleaning habit for the face or other areas of the baby's body. Wipes should be formulated to provide a minimum of interference with the functions of normal skin which is an important property in preventing skin infections (1-2). Continuous and excessive use of soap could be aggressive to the hydro-lipidic mantle and reduce the stratum corneum which is the first defence of the skin and could change skin pH (3-5). The aim of our study was to investigate that the regular use of baby wipes is safe and effective for skin cleaning during the change of diapers for the test phase (2 weeks).

MATERIALS AND METHODS

The study was carried out on 55 children, 56% of the subjects were male, 44% were female. Two randomly groups stratified according to the nine criteria below were formed by a personal computer, one of which was made of 28 subjects (Group 1, Test group), the other of 27 (Group 2, control group, with a commercially available product).

A pre-phase visit was made and the following parameters have been analyzed:

1) Sex and Mobility. The percent of males was 51% in the group 1 (49% of females) and 53% in the group 2 (47% of females).

The percent of subjects who walked without help was 61% in group 1 and 52% in group 2.

2) Breast feeding status. 93% of the subjects in group 1 were breast-fed, 85% in group 2.

3) Changes of the diet during the test. 4% of the subjects in group 1 changed their diet, 11% in group 2.

4) Teething. During testing none was observed in group 1, 11% in group 2.

5) Health condition. 19% of the subjects in group 1 and 8% in group 2 were affected by several illnesses (e.g. flu or cold) but none of them were severe enough to stop the test.

6) Regular use of drugs. In both groups none of the subjects have used drugs during the test period.

7) Use of systemic drugs before starting the test. 18% of the subjects made use of drugs in group 1, 4% in group 2, during the week before the product was tested.

8) Use of topically applied drugs in the diapered area. None of the subjects used ointments in the diaper area in group 1, 4% in group 2.

9) Presence of atopic dermatitis and seborrheic dermatitis (6) 4% of seborrheic dermatitis was found in group 1, none in group 2. No presence of atopic dermatitis was recorded in both groups.

DIAPERS

Babies, during the study, used uniform diapers provided by us. At the beginning of the test phase the wipes were provided in unlabelled packages and the mothers were trained in their use.

WIPES

TEST PRODUCT: it was made of a soft, thick air laid with 100% cellulose fibers substrate. The lotion was an oil in water emulsion. The oil phase was composed of emollient and spreading substances, in the water phase the preservative system was present.

CONTROL PRODUCT: in the control wipes the same substrate was present, as described above for the test product. The lotion was made of a water based solution with surfactant, emollient ingredients and the preservative system. Control product has been merchandise for many years.

CALIBRATION PHASE

With the aim of having the babies in the same skin conditions the babies' toiletries were carried out with a soap for 15 days before the beginning of the test (calibration phase, visit 1 to visit 2).

TEST PHASE (visit 2 to visit 3)

At the end of the calibration phase a baseline clinical evaluation was performed using several skin parameters (visit 2): clinical skin inspection with erythema evaluation ranging from 0 to 4 (0=absent, 1=slight, 2=moderate, 3=extended, 4=severe) and presence or absence of papules, vesicles and desquamation in the diapered area, pH measurement and microbiological culture. A questionnaire for the parents of the babies was also made. After 15 days use of the wipes the same parameters were evaluated (visit 3). visit 2 and visit 3 were performed by a dermatologist without the knowledge of which product was assigned to the baby. A standard pH-Meter (Beckman, Fullerton, CA, USA) was used and skin pH measurement was determined twice, after opening the diaper and after cleaning, on three sites inside the diaper area (symphysis pubis, right hip, buttocks) and one site outside the diaper area (thigh).

The measurements were performed only if the sites were not fecally soiled. Specimens for the microbiological test were taken on the buttocks with a swab (Cultiplast LP ITALIANA SPA, Milan, Italy). Microbiological analysis were carried out in an external laboratory. At the beginning of the test phase a questionnaire was gi-

ven to the mothers.

Questions were about practical, useful and pleasant aspects (or compliances) of the wipes. Questionnaires were given back at visit 3 with a personal comment about the products. For statistical analysis, all the values inside the diaper area were defined as the average of the sites values for symphysis pubis and right hip, and the net value were defined as the difference of the value inside the diaper area minus the value outside the diaper area. Furthermore an analysis has been performed for the buttocks pH values. Buttocks net values were defined as the difference of the value of the buttocks minus the value outside the diaper area.

The changes between visit 2 and visit 3 were the criteria for statistical analysis. Non-parametric test methods were used for the analysis of medical rash evaluation (Mann-Whitney-U test and Chi-square). Non-parametric and parametric test methods were used for the analysis of pH measurement (Mann-Whitney-U test and Student's t test). Values of $p < 0.05$ were considered statistically significant. Summarizing (see table 1) three visits were performed. visit 1: calibration phase of 15 days during which the babies were cleaned with soap and general clinical conditions were evaluated; visit 2: test phase with baseline clinical evaluation and use of wipes for 15 days; visit 3: final clinical evaluation on the last day of use of the product.

Table I
Clinical design of the study.

	WEEKS				
	0	1	2	3	4
Visit 1 Calibration phase				
	(Use of soap/water)				
Visit 2		 Test phase		
			(Use of test products)		
Visit 3				Final clinical evaluation	

RESULTS

Clinical evaluation

The medical rash grades for erythema has been analysed evaluating the grade obtained at visit 3 (after use of the products tested) compared to the grade at baseline, visit 2 (before the use of the products tested) for each product group. Results are summarized on table 2.

Product group 1 (new baby wipe).

The erythema was absent in the 89% of the subjects at both visit 2 and visit 3. 12% (3 cases) of the subjects presented slight erythema at visit 2; at visit 3, 8%(2 cases) of the subjects showed slight erythema and 4% (1 case) extended erythema. However, the differences between visit 2 and visit 3 were not statistically significant. Papules were noted in 4% (1 case) of subjects in both visit 2 and 3, no presence of vesicles or edema were recorded. 1 case (4%) of desquamation was present at visit 2, none at visit 3.

Product group 2 (control group).

Erythema was absent in 81% of the subjects at visit 2, in the 89% of the subjects at visit 3. At visit 2, 20% (5 cases) of the subjects presented slight erythema; at visit 3, 4% (1 case) of the subjects presented slight erythema, 4% extended erythema, 4% severe erythema. The differences between visit 2 and visit 3 were not statistically significant. The presence of papules was registered in the 12%

(3 cases) of the subjects in both visits 2 and 3. No presence of papules, vesicles and desquamation was diagnosed. 1 case (4%) of desquamation was registered at visit 2, no case at visit 3. In conclusion no influence of the product tested exists on the medical rash grading. Comparison between visit 2 and visit 3 for the medical rash grading didn't give evidence of any statistical significant differences in both product groups. In the only case with strong erythema, a patch test with the control product and the new product was done. Occlusive patches were applied on the left arm for 24 hours. The patches were removed and showed an extended erythema and slight vesicles only in the control product. The patch of the new product did not show any skin reaction.

Analysis of skin pH measurements

pH values - Product group 1

The average difference between the inside diaper area and outside diaper area was 0.07 in visit 2, 0.17 in visit 3, which is not statistically significantly different. The difference between the buttocks values and the external diaper site value (thigh) was 0.2 in visit 2, 0.26 in visit 3, which is not statistically significantly different. The same comparison for pH value after the cleaning of the same sites has been performed. No difference existed for both the average net values and the buttocks net

Table II
Clinical examination: comparison between before the use (visit 2) and after (visit 3).
In brackets the number of patients is indicated.

		erythema grade					Papules	Vesicles	Desquamation
		0	1	2	3	4			
Test product (28)	visit 2	(25)	(3)	-	-	-	(1)	-	(1)
	visit 3	(25)	(2)	-	(1)	-	(1)	-	-
Control Product (27)	visit 2	(21)	(5)	-	-	-	(3)	-	(1)
	visit 3	(23)	(1)	-	(1)	(1)	(3)	-	-

values between visit 2 and visit 3. In conclusion no influence of both the products tested existed for the pH values. The comparison between the average net values and the buttocks net values of visit 2 and visit 3 didn't give evidence of any statistically significant difference.

pH values - Product group 2

The average difference between the inside diaper area and outside diaper area was 0.12 in visit 2, 0.04 in visit 3, which is not statistically different. The difference between the buttocks values and the external diaper site value (thigh) was 0.23 in visit 2, 0.14 in visit 3, which is not statistically significantly different. The same comparison for pH value after the cleaning of the same sites has been performed. No difference exists for both the average net values and the buttocks net values between visit 2 and visit 3.

In conclusion no influence of both the products tested exists on the pH values. The comparison between the average net values and the buttocks net values of visit 2 and visit 3 didn't give evidence of any statistically significant difference.

Skin microbiology evaluation

The following elements have been investigated: Total Microbic Count (TMC), Proteus, Streptococcus Faecalis, Staphilococcus, Pseudomonas, Esherichia Coli, Fungi culture. Microbiological samples have been taken on the buttock area (4 cm²). The presence of microorganisms was qualita-

tively expressed by symbol "+" = growth of a small number of microorganisms; "++" = growth of a discrete number of microorganisms; "+++" = growth of a large number of microorganisms; "-" = negative.

Both groups gave the same results before and after product use (table 3). In conclusion very low TMC has been found after the use of wipes and products don't affect skin microbiology.

DISCUSSION

The continuous use of detergents on a sensitive skin such as a baby's skin could influence the skin barrier functions and defences against external agents (e.g. bacteria and fungi) (7-8).

Wipes are practical tools in baby cleaning in the modern times. The aim of this study was to assess whether the use of a new baby wipe could influence the skin conditions leading to skin irritative phenomena in comparison with the control group. Both products didn't show any statistical differences in laboratory analysis and clinical evaluation (except for a case of contact dermatitis). Clinically the skin showed a normal appearance with no increment of rashes or other lesions in both groups. pH measurements demonstrated slight differences not statistically significant. Microbiological specimens showed a low presence of total microbic count with a majority of Streptococcus Faecalis.

At the end of the study the skin was cleaner with very few microorganisms. From the questionnaire it resulted that the new baby wipe was best accepted for its moisture, smell and resistance. In conclusion both products were positively accepted by parents of the babies, and gave good results in cleaning with no alterations in physical characteristics of the epidermis.

*Author address: Dr. Claudio Feliciani
Clin. Dermatologica - Pol. "SS Annunziata"
Via dei Vestini, 66013 Chieti - Italy
phone +39-871-552310-551057
fax +39-871-551057
e-mail: felician@unich.it*

Table III

Microbiological test before and after the use of wipes.

	BEFORE	AFTER
Total Microbic Count (TMC)	+++	+
Proteus	-	-
Streptococcus Faecalis	++	-/+
Staphilococcus	+	-
Fungi	-	-
Pseudomonas	-	-
Escherichia Coli	-	-

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