

Clinical Evaluation of Bacteriostatic Soap in Diaper Dermatitis- Prophylaxis*

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Synopsis—A clinical study was conducted in the New York City area using 100 infants with a history of diaper rash but who were not suffering from diaper rash at the beginning of the study. Fifty infants were bathed with an antibacterial soap containing 0.75% hexachlorophene and 0.75% 3,4,4'-trichlorocarbanilide; 50 infants were bathed with the same soap without the presence of the antibacterial agents. In the case of the relatively common varieties of diaper rash, the severity and the incidence during the use of the antibacterial soap were significantly lower than that from the soap containing no antibacterial system.

INTRODUCTION

Diaper dermatitis continues to be one of the most common problems of pediatrics (1). At some time it occurs in almost all infants, and cases serious enough to warrant treatment account for 25% of all pediatric patients seen (2-4). This figure does not include the milder forms of irritation noted during well-baby checkups (5).

The etiology of diaper dermatitis is not entirely clear, though it is estimated that over 90% are due to contact dermatitis resulting from

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the interaction of urea with the gram positive rod *Bacillus ammonia-genes* (*Bacillus faecalis*) (6-8). Other bacilli (*coli*, *proteus*, *Aerobacter*, *Klebsiella*, *Pseudomonas* and *Staphylococcus*) have also been implicated in various forms of diaper dermatitis (2, 9).

In view of the frequency of diaper dermatitis and the acute discomfort it causes, any inexpensive, effective and simple form of prophylaxis would be a welcome addition to infant care (10).

The purpose of the present paper is to evaluate clinically the prophylactic effects of a bacteriostatic soap.* This soap (A) contains 0.75% 2,2'-dihydroxy-3,3',5,5',6,6'-hexachlorodiphenylmethane ("hexachlorophene") and 0.75% 3,4,4'-trichlorocarbanilide. It was compared with a similar soap (B) without the bacteriostatic agents, in a double blind test.

The effectiveness of hexachlorophene in the clearing and prevention of diaper dermatitis has previously been noted by other investigators (7, 11, 12).

Since the onset of diaper dermatitis is affected by a great variety of conditions (diet, general cleanliness, use of rubber pants, weather, sex, age, and characteristics of the infant) (14), it was felt that the statistical analysis of a large number of treated and untreated cases was the only way of demonstrating the clinical effect of the soap.

EXPERIMENTS AND RESULTS

Clinical Material

For the purpose of the study a group of 100 infants of both sexes, ranging in age from two months to 2½ years and having a case history of frequent episodes of diaper dermatitis, were selected. At the start of the experiment, all symptoms of diaper dermatitis were absent.

All but 16 of the test subjects used diaper service washed diapers.

Experimental Procedure

The infants were divided into two equal groups: Soap A was supplied to the mothers of one, Soap B to the other. Division into groups and distribution of the coded soap was based on the use of a random number table. Neither the clinician nor the mothers were aware of the nature of the soap used. The groups were balanced as far as sex and use of the diaper service were concerned.

The mothers were instructed to bathe the baby daily, being careful to cleanse the diaper area with the soap and soft cloth. Mothers were

* Dial soap, a product of Armour and Co., Chicago, Ill., was used.

permitted to use a moderate amount of nonmedicated talcum powder. No other form of treatment or medication was administered.

Clinical Evaluation

The test period lasted 28 days. During this time the infants were examined once a week. An evaluation (score) was made each time of the following symptoms: Types of diaper dermatitis present (erythema, eczematoid dermatitis, scaly dermatitis, ulcerative dermatitis, vesicular dermatitis); severity of symptoms ranging from 0-7 (0—absent, 1—almost absent, 2—very mild, 3—mild, 4—moderate, 5—moderate to severe, 6—severe, 7—very severe); and total diameter of dermatitis (in inches). The results were recorded on individual standard test forms.

Evaluation of Results

Clinical data of other investigators (1, 13) and examination of the results of this test indicated at once that sex and age play a significant role in the severity and incidence of diaper dermatitis. Both major subject groups were, therefore, subdivided into four subgroups classified as follows: Males (females) over (under) nine months. This age split was chosen because it divided the subjects into almost equal groups. A weekly average score was calculated for each of the resulting eight groups and for each type of diaper dermatitis under investigation.

Difference Among Soaps

The difference between the two soaps should be evaluated within the over-all framework of the experiment. The previous history of diaper dermatitis in the infants investigated in this study was used as a base line; the changes in the weekly score—determined as previously described—was the variable. Table I lists the changes in the weekly average score of erythema—by far the most common symptom of diaper dermatitis.

Comparison of the average previous score with the average weekly scores during the test period indicates that there is a drop of 2.30 (from 3.80 to 1.50) for the subjects using Soap A while there is a drop of only 1.38 (from 3.51 to 2.14) for the subjects using Soap B. The difference in these changes reflects the superiority of the bacteriostatic soap over the plain soap.

Tables similar to the one discussed were prepared for scaly dermatitis, eczematoid dermatitis, ulcerative dermatitis, vesicular dermati-

Table I
Summary of Average Scores for Erythema

	Previous	1st Week	2nd Week	3rd Week	4th Week
Soap A					
Male under 9 months	4.00	0.85	1.69	1.54	1.54
Male 9 months and over	4.30	1.50	2.30	1.70	2.60
Female under 9 months	3.64	0.55	1.27	1.09	2.36
Female 9 months and over	3.25	0.62	1.69	1.06	1.44
Total	3.80	0.88	1.74	1.35	2.02
Average:		1.50			
Soap B					
Male under 9 months	4.00	1.22	2.89	2.22	3.22
Male 9 months and over	2.92	1.31	2.38	2.69	2.69
Female under 9 months	3.75	1.50	2.50	1.90	2.30
Female 9 months and over	3.37	1.00	2.25	2.00	2.37
Total	3.51	1.26	2.50	2.20	2.64
Average:		2.14			

tis and the average rash diameter. In summary, it may be stated that the statistical results for erythema, scaly dermatitis and the diameter of the rash are very similar. In all cases the reduction of the severity and incidence of the diaper dermatitis is significantly greater with Soap A than with Soap B.

Eczematoid, ulcerative and vesicular dermatitis represent fairly uncommon symptoms, and their incidence among test subjects was consequently low. The results do not indicate a superiority of Soap A over Soap B in the reduction of these types of dermatitis.

Detailed Analysis of Variance

Review of the raw data indicated that the particular soap used, the time period, sex, and age play an important role in the severity and incidence of diaper dermatitis. In order to eliminate any error which might arise from the unequal distribution of the number of experimental observations, the raw experimental data were subjected to a detailed statistical analysis utilizing a variance model with four factors (soap, time period, sex, age) and multiple observations per cell (15, 16).*

A detailed statistical analysis was carried out for each of the five symptoms of diaper dermatitis and also for the overall diameter of the

* This analysis was carried out by the firm of Peat, Marwick, Caywood, Schiller and Co., Chicago, Ill.

rash. In the cases of the five categories, the numerical coding (0-7) was used as the dependent variable.

In such an analysis the "level of significance" is an indicator of the likelihood that there is a difference among the categories within each factor. The higher the level of significance the more likely a difference exists among the categories. For values less than 90 it is customary to consider the results not significant (N.S.). Values greater than 99 are considered highly significant. Table II lists the analysis of variance of incidence and severity of erythema.

Table II
Analysis of Variance of Incidence and Severity of Erythema

Source of Variation	Degrees of Freedom	Square	Value	Level of Significance
Change with Soap A <i>vs.</i> change with Soap B	1	17.113	12.78	99.9
Soap	1	26.450	19.75	99.9
Time	4	90.254	67.40	99.9
Sex	1	19.602	14.64	99.9
Age	1	0.162	0.12	N.S.
Soap \times time	4	5.386	4.02	99.5
Soap \times sex	1	1.682	1.26	N.S.
Soap \times age	1	5.618	4.20	95.0
Time \times age	4	1.308	0.98	N.S.
Time \times sex	4	0.378	0.28	N.S.
Sex \times age	1	3.042	2.27	N.S.
Soap \times time \times sex	4	1.386	1.04	N.S.
Soap \times time \times age	4	1.212	0.91	N.S.
Soap \times sex \times age	1	4.802	3.59	90.0
Time \times sex \times age	4	0.496	0.37	N.S.
Soap \times time \times sex \times age	4	1.788	1.34	N.S.
Error	460	1.339

Table III
Significance Level of Change in Symptoms, Soap A *vs.* Soap B

Symptom	Level of Significance
Erythema	99.9
Scaly dermatitis	99.0
Eczematoid dermatitis	N.S.
Ulcerative dermatitis	N.S.
Vesicular dermatitis	N.S.
Total diameter of rash	99.5

The other symptoms were subjected to a similar analysis. The level of significance for the change with Soap A *vs.* change with Soap B for the various types of dermatitis is summarized in Table III.

DISCUSSION AND CONCLUSIONS

The nature of the experimental setup (the examination of the incidence and severity of diaper rash during a four week period immediately following a time when all symptoms were absent and its comparison with a previous score reflecting the most severe episode in the past) accounts for the improvement noted with "time" and "soap" (both kinds) and their highly statistical significance. Of practical and paramount importance in the present study is the high statistical significance of the "change with Soap A *vs.* change with Soap B" for the categories: Erythema, scaly dermatitis, and diameter of the rash.

The lower occurrence of statistically significant results for the more serious categories (and, in particular, the absence of a significant difference between the two soaps) reflects the paucity of data in these categories due to the very low incidence of these symptoms.

The finding in this study of a highly significant age and sex dependence of incidence and severity of diaper dermatitis corroborates previously reported results.

SUMMARY

The severity and incidence of diaper dermatitis during the use of germicidal commercial soap (A) was investigated over a period of 28 days and compared with those during the use of a nonmedicated soap.

For the relatively common varieties of diaper dermatitis symptoms (erythema and scaly dermatitis) and the over-all diameter of the rash there was a significant reduction in the average severity and incidence when Soap A was used.

For the less common and more serious varieties of symptoms (eczematoid dermatitis, ulcerative dermatitis, and vesicular dermatitis) the reduction in average severity and incidence by the medicated soap was not significantly different from the comparable reduction with ordinary soap.

The average severity and incidence of all varieties of diaper dermatitis is significantly higher in males than in females and, among both males and females, among the older (9 months and over) infants.

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