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Original Research Article

Comparative evaluation of the clinical effects of high Air-Through soft diaper and standard diaper in Indian babies with diaper rash

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ABSTRACT

Background: The incidence of diaper dermatitis (rash) in India is reported to be in the range of four to thirty-five per cent in children up to 2 years of age.

Materials and Methods & Objective : To evaluate the clinical effect of using High Air-Through Soft Diaper and babies' favourite diaper (Standard diaper) on Indian babies' skin.

Design: This was a single-blinded, randomized, controlled, cross-over study. Eligible babies were randomized in two treatment groups. Babies in Group A used High Air-Through Soft Diaper for the first two weeks and then used standard diaper for the next 2 weeks. Babies in Group B used a standard diaper for the first two weeks and then used a High Air-Through Soft Diaper for the next 2 weeks.

Study population: The study was completed with 105 babies.

Primary endpoints: The evaluation of the skin using the scoring system and photographs for representative purposes.

Results: At baseline, the mean total diaper rash scores were comparable in both Group A and Group B viz. 3.04 ± 1.00 and 3.30 ± 1.04 respectively and the difference was not statistically significant ($p = 0.195$). After 2 weeks, the mean total diaper rash score increased significantly from the baseline in both Group A and Group B (5.05 ± 1.97 ; $p = 0.001$ and 6.16 ± 2.22 , $p = 0.001$ respectively); the rise in the mean total diaper rash score was significantly more in Group B than that in Group A ($p = 0.045$). After 4 weeks, a significant increase in the mean total diaper rash score (1.31 ± 2.69 ; $p = 0.001$) was observed from what it was at 2 weeks in the Group A and there was an insignificant decrease in the mean total diaper rash score (-0.52 ± 2.54 ; $p = 0.153$) in Group B from what it was at 2 weeks; the change in the mean total diaper rash score was significantly more in Group A than that in Group B ($P = 0.001$).

Conclusions: Both High Air-Through Soft Diaper and standard diaper in babies caused a significant increase in mean total diaper rash score. However, the extent and the degree of rash induced with the use of High Air-Through Soft Diaper was significantly less than that during the usage of the standard diaper. Thus, High Air-Through Soft Diaper due to technologies used in it appears to be superior to the standard diaper in reducing the mean total diaper rash score.

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1. Introduction

Diapers have been an important component of the lives of babies for the past fifty years.¹ A variable incidence of diaper dermatitis (rash) is reported in studies.² The incidence of diaper dermatitis in India is reported to be in the range of four to thirty-five per cent in children up to 2 years of age.³ The following factors contribute to the increased prevalence of diaper dermatitis: humidity, non-breathability, adherence of excreta to the skin, weaker infant's skin barrier, skin rubbing.⁴ It is difficult to prevent Diaper rash completely.⁵ Disposable diapers play an important role to prevent diaper rash.⁶⁻⁸

The current study was conducted in India to compare the effect of technologies used in High Air-Through Soft Diaper to that of the favourite brand diaper (Standard diaper) used in India.

2. Materials and Methods

2.1. Study objective

Primary objective was to evaluate the clinical effect of using High Air-Through Soft Diaper and babies' favourite diaper (Standard diaper) on babies' skin.

2.2. Study design

This was a single-blinded, randomized, controlled, cross-over study. Eligible babies were randomized in two treatment groups. A randomization software was used for making the balance of skin assessment scores, gender and age of month of babies.

2.3. Ethical approval

This study was approved by the institutional ethics committee before the conduct of the study.

2.4. Recruitment of babies

The baby's mother was given detailed oral and written information concerning the study. If the baby's mother was willing to allow her baby to participate in this study, written informed consent from the mother was obtained. After the informed consent form was signed, the mother was requested to fill up the biodata form or demographic data form and answer the questionnaire.

Inclusion criteria for the recruitment of babies in the study were as follows: a) 3 - 24 months babies using disposable diapers only, b) Babies using the standard diaper as their favourite diapers every day, the standard diaper which is the most commonly used as a favourite diaper in India, at least 3 disposable diapers within 24 hours c) The parent willing to provide written informed consent to

participate in the study, d) Babies without diaper rash and with mild diaper rash (skin evaluation score 0-2, at least score 2 at one place). Normal healthy participants were selected for the study. These participants were not under any prior or concomitant therapy.

Exclusion criteria for not recruiting babies in the study were as follows: a) Any kind of skin rashes other than diaper rash, b) Babies with atopic dermatitis, c) Presence of systemic illness, d) Babies on the treatment for their skin problems

2.5. Assessment of the test products

Babies in Group A used High Air-Through Soft Diaper for the first two weeks and then used Standard diaper which is the same as their favourite diaper for the next 2 weeks. The standard diaper is the most used in India, so it is suitable as the control product for this study. Babies in Group B used Standard diaper which is the same as their favourite diaper for the first two weeks and then used High Air-Through Soft Diaper for the next 2 weeks.

2.6. Data collection and follow-up

One hundred and fourteen eligible babies were recruited in two treatment groups. The study was completed with 105 cases. There were 9 dropouts.

As shown in Figure 2, based on the data of the questionnaire, interview, and dermatological examination, babies were subsequently screened according to the eligibility criteria. The investigator evaluated subject eligibility compared to inclusion and exclusion criteria. Babies were qualified to continue to be involved in the study procedure (treatment phase) if they fulfilled all the criteria.

The following were the aspects of the study procedure: Visit 1 (Day 0): Screening of the baby, a pre-survey questionnaire to be filled up, to do the dermatological examination, the inclusion of a baby into the study, to take the medical history, to do visual skin assessment, to take photographs, body measurements, to dispense the first investigational product, to prepare a daily log sheet, to give instructions to mother about product usage. Visit 2 (Week 2): a post-survey questionnaire to be filled up, to take photographs, to do visual skin assessment, to dispense the second investigational product, to prepare a daily log sheet and to collect remaining (used) products. Visit 3 (Week 4): a post-survey questionnaire to be filled up, to take photographs, to do visual skin assessment, to prepare a daily log sheet and to collect remaining products.

2.7. Efficacy evaluation

Primary endpoints of the study were as follows: The evaluation of the skin using the scoring system (Table 1) and photographs for representative purposes.

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Parameters taken into account for the analysis were erythema, desquamation and papula and immerse/erosion and the evaluation areas were as follows: waist (front and back), buttock (right and left), pubic region, anal region, root of the thigh (right and left); the maximum score was considered for the waist (front and back), buttock (right and left) and root of the thigh (right and left). Total diaper rash score was calculated by adding the scores of all parameters for all areas. The mean of the total diaper rash score was calculated. For the analysis of this study, we analysed all the symptoms that appeared in each body part inside the diaper to understand the trend of symptoms in each part, since the parts where symptoms appeared and what kinds of symptoms appeared were different and these depended on the individual.

2.8. Product compliance

The diapers were collected and counted at the study centre on the days of visits, to check for the compliance. The number of remaining diapers was noted down in logs.

2.9. Statistical analysis

The data of 105 participants were analysed. The statistical analysis was carried out by 10.0 version of statistical software SPSS and at 95% level of significance. The following tests of significance were used: Student t-test and chi-square test.

3. Results

Table 2 demonstrates the demographic data. The mean age in both the groups (Group A and Group B) was 12.82 months and it was not significantly different ($P > 0.05$). There was no significant difference ($P > 0.05$) in the number of male and female babies involved in the study.

3.1. Efficacy evaluation

The results regarding the mean total diaper rash score are shown in Table 3. At baseline, the mean total diaper rash scores were comparable in both Group A (Initially High Air-Through Soft Diaper and then standard diaper) and Group B (Initially standard diaper and then High Air-Through Soft Diaper) viz. 3.04 ± 1.00 and 3.30 ± 1.04 respectively and the difference was not statistically significant ($P = 0.195$). After 2 weeks, the mean total diaper rash score was increased significantly from the baseline in both Group A and Group B (5.05 ± 1.97 ; $p = 0.001$ and 6.16 ± 2.22 , $p = 0.001$ respectively); the rise in the mean total diaper rash score was significantly more in Group B than that in Group A ($P = 0.045$) after 2 weeks. After 4 weeks, a significant increase in the mean total diaper rash score (1.31 ± 2.69 ; $p = 0.001$) was observed from what it was at 2 weeks in the Group A and there was an insignificant decrease in the mean total

diaper rash score (-0.52 ± 2.54 ; $p = 0.153$) in Group B from what it was at 2 weeks; the change in the mean total diaper rash score was significantly more in Group A than that in Group B ($P = 0.001$).

Figure 3 is a graphical representation of changes in mean total diaper rash score between groups and results indicate that High Air-Through Soft Diaper is significantly better than Standard diaper at week 2 and week 4 as mean total diaper rash score was significantly less with the use of High Air-Through Soft Diaper.

3.1.1. Safety evaluation

There were no other adverse events reported during the entire study duration with any baby.

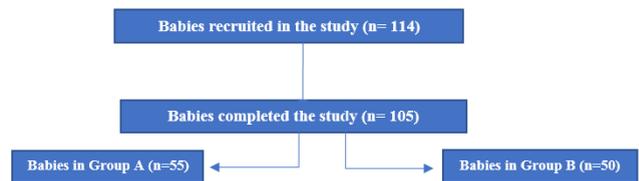


Fig. 1: Summary of the babies involved in the study

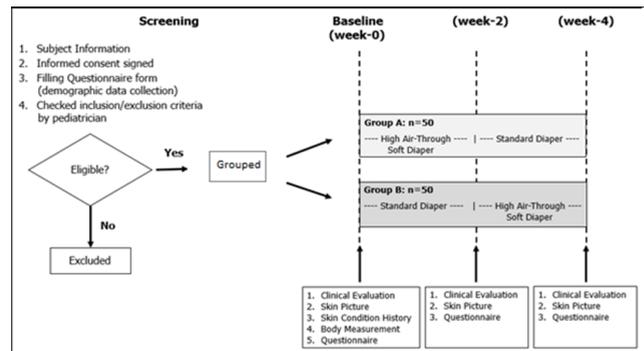


Fig. 2: The flow chart of the study.

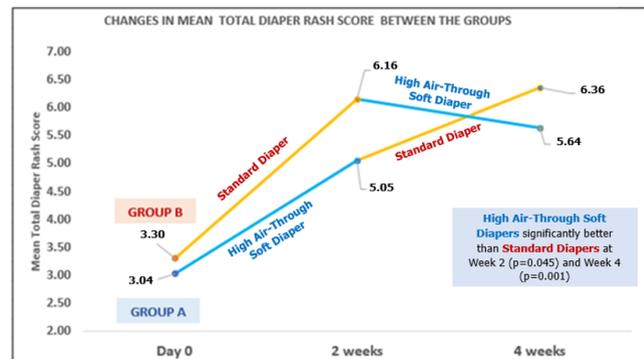


Fig. 3: Changes in mean total diaper rash score between groups.

Table 1: Skin evaluation scoring system⁴

Score	Erythema/edema	Papule/pustule	Immerse/erosion	Desquamation
0	Absent	Absent	Absent	Absent
1	Very slightly erythema, area < 2%	Only one site	Slight immerse, area < 2%	Slight desquamation, area < 2%
2	Very slightly erythema, area (2-10%) or slight erythema, area < 2%	Discrete papule, 2-5 sites	Slight immerse, area (2 -10%)	Slight desquamation, area (2 - 10%)
3	Very slightly erythema, area > 10% or slightly erythema, area (2-10%) or obvious erythema < 2%	Discrete papule, area < 10%	Slight to moderate immerse, area > 10% or slight erosion, area < 2%	Slight to moderate desquamation, area > 10%
4	Slight erythema, area (10 - 50%) or obvious erythema, area < 2% with edema	Moderate papule, area (10 - 50%) or pustule (0 to 5 sites)	Moderate immerse, area (10 - 50%) or slight erosion, area (2 - 10%)	Moderate desquamation, area (10 - 50%)
5	Obvious erythema, area > 50% or obvious erythema, area (2 -10%) with edema	Moderate to severe papula, area > 50% or pustule (over 5 sites)	Moderate to severe immerse, area > 50% or moderate erosion, area > 10%	Moderate to severe desquamation, area > 50%
6	Obvious erythema, area > 10 % with edema	Large area confluent papula or large pustule/blister	Severe erosion, area > 50% or ulcer, necrosis	Severe desquamation

Source: Yuan C, Takagi R, Yao XQ, Xu YF, Ishida K, Toyoshima H. Comparison of the Effectiveness of New Material Diapers versus Standard Diapers for the Prevention of Diaper Rash in Chinese Babies: A Double-Blinded, Randomized, Controlled, Cross-Over Study. Biomed Res Int. 2018;2018:5874184. Published 2018 Jun 24. doi:10.1155/2018/5874184

Table 2: Demographic data

Parameters	Group A	Group B
No. of cases	55	50
#Age (months)		
Mean	12.82	12.82
SD	5.61	6.75
Range	3 – 24 months	3 – 23 months
@Gender (%)		
Male	29 (52.7)	27 (54.0)
Female	26 (47.3)	23 (46.0)
#By Student t-test P >0.05, not significant @By Chi-Square test, SD = Standard deviation		

Table 3: Total diaper rash score

Duration (Weeks)	Mean total diaper rash score (X SD)		p -value
	Group A(N = 55)	Group B(N = 50)	
Baseline	3.04 1.00	3.30 1.04	0.195 (NS)
2	5.05 1.97	6.16 2.22	
4	6.36 2.30	5.64 1.78	
Mean diff (Baseline – 2 weeks) (p value)	*2.02 1.95 (0.001)	*2.86 2.26 (0.001)	*0.045
Mean diff (2 weeks – 4 weeks) (p value)	*1.31 2.69 (0.001)	-0.52 2.54 (0.153) NS	*0.001

By Student t Test p >0.05; SD = Standard deviation; *Significant; NS = Not significant; Mean diff - Mean difference

4. Discussion

The present study is the first study to compare the effectiveness of two disposable diapers (High Air-Through Soft Diaper and Standard diaper) for assessing the effect on the skin and total diaper rash score in India.

It was found in a study conducted in China by Yuan C et al. that the new material diaper had superiority over the standard diaper in China in preventing diaper rash in babies. The design of this study was similar to that current study. In the study by Yuan C et al., the mean evaluation score of the anal region was almost similar in both the groups by 2 weeks. However, the result indicated an improvement in the mean evaluation score of the anal region with the new material diaper than that with the standard diaper by the end of 4 weeks. However, the advantage in the current study is that the mean of the total diaper rash score was calculated. Total diaper rash score was calculated by adding the scores of all parameters for all the areas wherever the diaper was adhered to. Thus, the current study appears to be more conclusive.⁴

In the present study we found that, after 2 weeks, the mean total diaper rash score was increased significantly from the baseline in both Group A (High Air-Through Soft Diaper- Standard diaper) and Group B (Standard diaper-High Air-Through Soft Diaper). We mention at the end, these first 2 weeks results were also affected by increasing environmental temperature. Since the standard diaper was the same as the subjects' favourite diaper, the subjects in Group B continued to use the same diaper in the study which was a favourite diaper before the test until week 2, and it was expected that the score would not change much. But the mean total diaper rash score was increased despite continued use of the same diaper in Group B might suggest that the skin condition of infants is greatly affected by the weather. However, even in such increased environmental temperature, the rise in the mean total diaper rash score was significantly less in Group A than that in Group B. After 4 weeks, the mean total diaper rash score was increased significantly from what it was at 2 weeks in the Group A and there was an insignificant decrease in the mean total diaper rash score in Group B from what it was at 2 weeks.

Studies show that the skin barrier functions of babies are altered with the design and materials of the diaper.^{4,9} A common disposable diaper is composed of a top sheet, an absorbent core, gathers, and a leakage-proof sheet. The standard disposable diaper may cause damped skin due to spread of sweat or urine and faeces and their adherence to skin that lead to skin irritation that eventually leads to the incidence of diaper rash.¹⁰

It has been proven in controlled studies that breathable disposable diapers are associated with reduced diaper dermatitis than that with standard, non-breathable disposable diapers possibly because of the following aspects: 1. The high-quality materials help in detaching

urine and faeces from getting attached with the skin 2. Reduced humidity in a disposable diaper if diapers are changed in time.¹⁰

4.1. High Air-Through Soft Diaper vs standard diaper

High Air-Through Soft Diaper is composed of: airy waist channel, high breathable leak-proof sheet, soft and low-density inner surface sheet, two-layer absorbent sheet with thick grooves.

Unlike the standard diaper, the High Air-Through Soft Diaper has air channels on the waist part. The air channels allow the waist skin and diaper to contact each other in a striped pattern rather than the entire surface, and the air tunnels of the high breathable leak proof sheet help in emitting the moisture out of the diaper. On the other hand, the standard diaper doesn't have air passing-way in the waist part like the air channels. The waist part of the standard diaper is adhered to the skin and the diaper by rubber material in the waist part, so the moisture in the diaper may not be possibly escaped outside. So, High Air-Through Soft Diaper is very good performant in terms of breathability.

The humidity inside the diaper can be more than 80% after urination. If the damped condition remains in the diaper, bacteria such as *Candida* grows easily.¹¹ The High Air-Through Soft Diaper has the full-scale breathable leak-proof sheet, so even after urination, the urine does not leak out and High Air-Through Soft Diaper can continue to discharge moisture to the outside in all the directions through lots of air tunnels in the airy channel and fully breathable leak-proof sheets. Whereas, the standard diaper is very easy to get damped because it has no air channels and no breathable sheet. These technologies of the diaper are presumed that the High Air-Through Soft Diaper can reduce the stuffiness inside the diaper. Due to these differences in both the diaper structures, High Air-Through Soft Diaper may have kept the babies' skin as hygienic in the present study by maintaining a less-humid environment inside the diaper.

It is known that not only humidity in the diaper but also rubbing between the diaper and the skin and attaching excrement to the skin make the barrier function of the skin to be reduced and cause irritation. Compared to the standard diaper, the High Air-Through Soft Diaper is made of a very soft low-density material sheet considering babies' skin. This sheet has a structure in which soft fibres are layered so that the friction between the skin and the diaper surface does not take place easily, and the damage due to the skin rubbing can be reduced or prevented and it was expected that the barrier property of the skin can be maintained because of that. Moreover, this low-density surface sheet has a lot of space in the sheet, so that excrement passes through the sheet easily. Moreover, the top sheet of this High Air-Through Soft Diaper for low-aged babies has a wavy-

shaped 3D structure in addition to the low-density structure, it makes the soft stool of low-aged babies which is easy to spread quickly absorbed and less spread on the surface of the diaper, so it can minimize the contact between the stool and the skin.

As mentioned previously, High Air-Through Soft Diaper has the two-layer structure in the excreted area such as the pubic area and the perianal area, and it contains the wide groove from the pubic area to the buttock area. Due to these features, even a large amount of urine and stool can be quickly absorbed by the two-layer absorber through the thick grooves. Whereas, the absorbent core of the standard diaper has a one-layer structure that may have a lesser absorbent capacity.

In the present study, the above-mentioned features of High Air-Through Soft Diaper may have protected the babies' skin from irritation and suppressed the skin troubles as compared to that with the standard diapers. The new material diaper used in the study conducted by Yuan C et al. also had similar features. Therefore, High Air-Through Soft Diaper in the present study also showed similar superiority over the standard diaper in babies as that observed in the study conducted by Yuan C et al.⁴

There are some limitations to the present study. Climate factors are confounding factors in such types of studies as they have effects on skin irritation and skin barrier functions. However, both the groups were exposed to the same climate factors in the current study and some of the aspects regarding climate factors are discussed further in this article. The environmental temperature during the conduct of this study can be a confounding factor that may affect the skin barrier function; this environmental factor was uncontrollable during the entire study period. However, it is understood that both groups had gone through similar weather conditions throughout the study. The environmental temperature was increased from week 0 to week 2 during this test period. The increased environmental temperature may have caused a significant increase in mean total diaper rash scores in both the groups (High Air-Through Soft Diaper and Standard diaper). As mentioned previously, since the standard diaper was the same as the subjects' favourite diaper, it was expected that the score would not change much. But the mean total diaper rash score was increased despite continued use of the same diaper in Group B might suggest that the skin condition of infants is greatly affected by the weather. However, even in such increased environmental temperature, the rise of mean total diaper rash score was suppressed more during the use of High Air-Through Soft Diaper than that during the use of the standard diaper. Therefore, it may be considered that High Air-Through Soft Diaper contributes to suppressing the mean total diaper rash score during the period of increased environmental temperature.

5. Conclusion

The continuous use of both High Air-Through Soft Diaper and standard diaper in babies caused a significant increase in mean total diaper rash score in the first half period of this study. In the last half period of this study, the standard diaper caused a significant increase in mean total diaper rash score, however High Air-Through Soft Diaper caused an insignificant decrease in the mean total diaper rash score. The extent and the degree of rash in the last half period induced by usage of High Air-Through Soft Diaper were significantly less than that during the usage of the standard diaper. Thus, High Air-Through Soft Diaper due to technologies used in it appears to be superior to the standard diaper in reducing the mean total diaper rash score.

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7. Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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