A randomized, controlled, cross-over study of the safety and efficacy of super-absorbent diaper for babies with mild-to-moderate diaper rash

Inne Arline Diana,¹,² Srie Prihianti Gondokaryono,¹,² Titi Lestari Sugito,¹ Maya Devita Lokanata,¹ Triana Agustin,¹,³ Githa Rahmayunited,¹,³ Indah Maharani,¹ Nanny Shoraya,¹,⁴ Haruko Toyoshima,⁵ Danang Agung Yunaidi⁶

ABSTRACT

BACKGROUND Super-absorbent diaper is a disposable diaper with new technology which has a soft-airy structure, breathable sheet, and rich absorbent core. This study aimed to compare the safety and efficacy of super-absorbent diaper with standard absorbent diaper.

METHODS A single-blinded, randomized, controlled, cross-over study was performed in 3–24 months babies. A safety study was performed in 113 babies without diaper rash (group A: super-absorbent to standard and B: standard to super-absorbent) and efficacy study in 59 babies with mild-to-moderate diaper rash (group C: super-absorbent to standard and D: standard to super-absorbent). Each group used super-absorbent or standard diaper for 2 weeks. Skin assessment scores (SAS) were recorded at baseline, week-2, and week-4. Non-parametric tests were used to analyze the data.

RESULTS In the safety study, there was no significant increase of SAS in group A at week-2 and -4, but in group B there was a significant increase of SAS (1.9 to 4.1, \( p = 0.001 \)) at week-2 with a significant reduction at week-4 (4.1 to 2.2, \( p < 0.001 \)). In the efficacy study, there was a reduction of SAS at week-2 in group C (\( p = 0.07 \)) and D (\( p = 0.05 \)). However, SAS increased in group C (6.4 to 8.3, \( p = 0.2 \)) and decreased in group D (8.6 to 6.1, \( p = 0.13 \)) at week-4. Super-absorbent diaper showed a significant reduction of SAS in the pubic areas (1.43 to 0.73, \( p < 0.011 \)).

CONCLUSIONS The new super-absorbent diaper is safe to use and may have efficacy in the improvement of skin conditions and diaper rash, especially in the pubic areas.

KEYWORDS efficacy, safety, super-absorbent diaper

Diaper rash is one of the most common dermatologic conditions in babies.¹⁻⁴ The etiology of diaper rash is multifactorial.¹⁻⁵ Its initiating factors are prolonged contact with feces (proteolytic and lipolytic digestive enzymes) together with increased wetness of the skin by urine.² This leads to an increased frictional damage, decreased barrier functions, and increased reactivity to irritants. Other interrelated etiologic factors include an increased skin pH and superinfection with Candida and less commonly, with bacteria.¹⁻⁵ There has been a high reduction in the prevalence and severity of diaper rash during the last several decades. Specifically, the frequency of severe rash has decreased because of the technological advances in the Western cloth diapering practices such as the initial use of cellulose disposable diapers that was subsequently followed by the introduction of disposable diapers with super-absorbent cores and breathable covers.⁵⁻⁷

Super-absorbent diaper was designed using a novel technology to provide a soft-fit structure; more
breathable structure at the waistband, pubic area and buttock; with slit and rich absorbent core in the front to provide increased dryness. This study was aimed to evaluate the safety and efficacy of the super-absorbent diaper with newly improved technological features compared with the standard diaper, for mild-to-moderate diaper rash.

**METHODS**

This study was single-blinded, randomized, controlled, and cross-over. The investigators were blinded for the type of diapers used by the subjects. The investigation group consisted of babies aged 3–24 months. The inclusion criteria were as follows: 3–24 months old babies using disposable diapers only, diaper rash score was 3–4 in any area (mild-to-moderate diaper rash) or 0–1 in each area (without diaper rash) according to skin assessment scores (SAS) in Table 1, and the willingness of the parent to provide written informed consent to participate in the study. The exclusion criteria included any kind of dermatoses, babies with atopic dermatitis, presence of systemic illness, and babies receiving treatment for dermatoses. During the study, all babies were equally treated with the same baby soap for the diaper area and mothers were instructed to change the diaper at least every 6 hours.

The safety study included 113 healthy babies, who were divided into 2 groups (A and B). Group A used the super-absorbent diaper for 2 weeks, and then switched to the standard diaper for another 2 weeks. Group B used the standard diaper for 2 weeks and then switched to the super-absorbent diaper for another 2 weeks.

The efficacy study included 59 babies with mild-to-moderate diaper rash, who were also divided into 2 groups (C and D). Group C used the super-absorbent diaper in the first 2 weeks and then switched to the standard diaper for another 2 weeks. Group D used the standard diaper in the first 2 weeks and then switched to the super-absorbent diaper for another 2 weeks. The drop-out criteria was worsening of the diaper rash.

SAS were calculated in both healthy babies and babies with mild-to-moderate rash, which consisted of scoring for erythema, papules, erosion, and desquamation, done in 6 areas (waist front and

| 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 (0–5 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 papule, area >50% or pustule (>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 papule or large pustule/blister | Severe erosion, area >50% or ulcer, necrosis | Severe desquamation |

Table 1. Skin assessment scores (SAS)

Reproduced from: 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. Under the Creative Commons Attribution License (CC BY 4.0) https://creativecommons.org/licenses/by/4.0/
back, buttock, pubic region, anal region, and root of thigh) at baseline, week-2, and week-4 (Table 1). This assessment was performed by dermatologists. The same baby soap was used in all the babies and the mothers were instructed on when to change the diapers and clean with wet cotton balls. Other skincare products such as baby wipes or baby creams were not allowed during the study. The babies used at least 2 diapers within 24 hours.

Prior to the study, written informed consent from the parents or legal guardians of the participants were obtained and the study received ethics approval from the Health Research Ethics Committee, Faculty of Medicine Universitas Indonesia, Cipto Mangunkusumo Hospital (No: 411/H2.F1/ETIK/2014). The trial was conducted at PT Equilab International, Jakarta, Indonesia.

Descriptive statistics were done for tabulated raw data only (mean, minimum, maximum, and standard deviation). Wilcoxon signed-rank test and Mann–Whitney U test were used to analyze the SAS data of within and between the treatment groups, respectively.

**RESULTS**

Figure 1 shows the flowchart of the study. A total of 195 babies were assessed and only 177 were eligible for the study, 117 of them were allocated for safety study and 60 babies were allocated for efficacy study.

**Demographics**

The demographic data of the subjects were similar in terms of age, sex, skin lesions, and total numbers of babies for the safety and efficacy studies (Table 2).

**Safety study**

A safety study was done on 113 healthy babies without any skin lesions on the diaper area or any
other skin lesion, which could influence the skin conditions in the diaper area. SAS was used to evaluate the safety. Skin care in the diaper area, in this case, total daily diaper changes, and the amount of baby soap used daily were equal in both groups. The total diaper changes per day (average: 4.7–5.0 pieces/day) and the total amount of baby soap used per day (average: 9.9–10.8 ml/day) were same in groups A and B (Table 3).

The results of the safety study are shown in Figure 2a. Group A showed no significant changes in the total SAS from baseline to week-2 (\( p = 0.09 \)) and from week-2 to week-4 (\( p = 0.35 \)). Group B showed a significant increase in the total SAS from 1.9 at baseline to 4.1 at week-2 (\( p < 0.001 \)). However, after using super-absorbent diaper, there was a significant decrease in the total SAS from 4.1 to 2.2 (\( p < 0.001 \)) from week-2 to week-4.

### Efficacy study

An efficacy study conducted in 59 babies with a mild-to-moderate diaper rash. SAS was used to evaluate the efficacy. Skin care on the diaper area, in this case, total daily diaper changes, and the amount of baby soap used daily were equal in both groups C and D. The total number of diaper changes per day (average: 4.9–5.1 pieces/day) and the total amount of baby soap used daily (average: 9.0–10.7 ml/day) were same in groups C and D (Table 3).

The results of the efficacy study are shown in Figure 2b. Group C and D both showed a decreasing tendency in the total SAS from baseline to week-2 (\( p = 0.07 \) and \( p = 0.05 \)). However, group C showed an increase in the total SAS, 6.4 to 8.3 (\( p = 0.2 \)) from week-2 to week-4, whereas group D showed a continuous decrease in the total SAS, 8.6 to 6.1 (\( p = 0.13 \)) in the same period.

### SAS of specific areas

The SAS of all the 6 areas evaluated are shown in Figure 2c–e. Evaluation on the waistband area in group C showed a decrease in the total SAS from baseline to week-2 (\( p = 0.07 \) and \( p = 0.05 \)). However, group C showed an increase in the total SAS, 6.4 to 8.3 (\( p = 0.2 \)) from week-2 to week-4, whereas group D showed a continuous decrease in the total SAS, 8.6 to 6.1 (\( p = 0.13 \)) in the same period.

### Table 2. Demographic characteristics of the subjects

| Variable                    | Group A, n (%) (N = 58) | Group B, n (%) (N = 55) | Group C, n (%) (N= 30) | Group D, n (%) (N= 29) |
|-----------------------------|-------------------------|-------------------------|------------------------|------------------------|
| Male sex                    | 30 (51.7)               | 30 (54.5)               | 17 (56.7)              | 15 (51.7)              |
| Age (months)                | 3–24                    | 3–24                    | 3–24                   | 4–24                   |
| Skin conditions             | Healthy                 | Healthy                 | Mild–moderate diaper rash | Mild–moderate diaper rash |
| Skin assessment score       |                         |                         |                        |                        |
| Week-0                      | 20 (34.5)               | 14 (25.5)               | 14 (46.7)              | 17 (58.6)              |
| Week-2                      | 24 (41.4)               | 16 (29.1)               | 20 (66.7)              | 16 (55.2)              |
| Week-4                      | 23 (39.7)               | 19 (34.5)               | 12 (40.0)              | 19 (65.2)              |

Group A=super-absorbent to standard; group B=standard to super-absorbent; group C=super-absorbent to standard; group D=standard to super-absorbent

### Table 3. Total diaper changes and baby soap using per day of safety and efficacy study

|                     | Safety study     |                      |                      | Efficacy study   |
|---------------------|------------------|----------------------|----------------------|------------------|
|                     | Group A (N = 58) | Group B (N = 55)     | Group C (N = 30)     | Group D (N = 29) |
| Diaper (pc/day)     | Week-0 to week-2 | 4.7                   | 4.7                   | 5.1              | 4.9              |
|                     | Week-2 to week-4 | 4.9                   | 5.0                   | 5.1              | 4.9              |
| Soap (ml/day)       | Week-0 to week-2 | 10.1                  | 9.9                   | 9.2              | 9.0              |
|                     | Week-2 to week-4 | 10.8                  | 10.2                  | 10.7             | 10.0             |

Group A=super-absorbent to standard; group B=standard to super-absorbent; group C=super-absorbent to standard; group D=standard to super-absorbent

mji.ui.ac.id
0.73, \( p = 0.011 \)), and after switching to the standard diaper, there was no significant decrease in the SAS. In group D, the first 2 weeks of using the standard diaper showed a decrease in the SAS (1.82 to 1.29, \( p = 0.135 \)), but it was not significant. However, after switching to super-absorbent diaper, there was a significant decrease in the SAS from 1.29 to 0.41 (\( p < 0.049 \)) from week-2 to week-4.

Evaluation of the buttock area showed that there were no significant differences at baseline, week-2 and week-4 in group C. However, after switching to the standard diaper, there was a slight increase in the SAS from week-2 (0.93) to week-4 (1.87). In group D, the SAS at baseline significantly decreased from 2.57 to 1.39 in week-2 (\( p = 0.033 \)) and continued to decrease to 0.81 after switching to super-absorbent diaper.

**DISCUSSION**

It is known that the use of disposable diapers can prevent the occurrence of diaper rash. A modern disposable diaper is composed of a top sheet, an absorbent core, gathers, and breathable sheets. However, sometimes even after using a disposable diaper, the skin may still be damped by sweat or pee and thus irritates the skin; resulting in the development of diaper rash.⁸ This condition maybe accentuated in hot and humid environmental conditions, like in Indonesia.⁹ In addition, less frequent diaper changes also have a role in the pathogenesis of diaper rash.

To overcome these issues, a new technology diaper was created called the super-absorbent diaper. The diaper was composed of: (1) soft-fit structure...
which consist of soft fit waist gathers and illium

In this study, the mothers were instructed to

The safety study results showed that in group

Regarding the efficacy in mild-to-moderate
diaper rash, both diapers were shown to improve
the skin rash in the first 2 weeks because there was
a decrease in the mean total SAS. On the one hand,
between week-2 and week-4, there was no further
improvement after switching to the standard diaper
in group C and the mean total SAS tended to increase,
although it was not significant. On the other hand,
there was further improvement after switching to
the super-absorbent diaper in group D, as indicated
by a decrease in the mean total SAS.

In the evaluation of the 6 areas which were scored
during this study, pubic areas showed a significant
improvement with the use of super-absorbent diaper
compared with the standard diaper. There was a
significant improvement in the skin rash on the

Clinical evidence supports that modern
disposable diaper technology can overcome the
negative impacts of overhydration, increased pH,
friction, and other factors that can damage the skin
integrity as well as decrease the severity of diaper
dermatitis. According to several clinical studies,
moderate to severe diaper dermatitis was 50% declined after the introduction of modern diaper.

Such an improvement in diaper products is likely
to contribute in lowering the incidence of diaper
rash. Moreover, frequent diaper changes and proper skin care, as instructed to the mothers, also play an essential role in improving the skin condition and thus the diaper rash.

The limitation of this study is that objective parameters such as transepidermal water loss (TEWL) and skin capacitance as well as the temperature and humidity in the subject's environment were not measured. In conclusion, the new super-absorbent diaper is safe to use and can contribute in improving the skin condition. Both diapers showed a tendency to improve diaper rash. The super-absorbent diaper may further improve diaper rash, especially on the waistband and pubic areas. To further elucidate the physiological changes of the skin after diaper usage, other objective parameters such as TEWL, skin capacitance, and environmental temperature and humidity can be measured.

Conflict of interest

Inne Arline Diana, Srie Prihianti Gondokaryono, Titi Lestari Sugito, Maya Devita Lokanata, Triana Agustin, Githa Rahmayunita, Indah Maharani, and Nanny Shoraya received grant support through their institution (Indonesian Society of Dermatology and Venereology). Haruko Toyoshima was employee of KAO Corporation Japan and Danang Agung Yunaidi was employee of PT Equilab International Jakarta at the time of the conduct of this study and manuscript preparation.

Acknowledgment

The authors acknowledge all participating babies and their parents for taking part in this study. The authors would like to thank (late) Prof. Arnold P. Oranje, pediatric dermatologist, in the Netherlands poliklinik (kinder) HUID en HAAR, and Breda Dermicis Skin Clinics, the Netherlands, for the construction help and power of valuable assistance in English language editing of the article.

Funding Sources

This study was funded by KAO Corporation, Japan.

REFERENCES

1. Hunt R, Chang MW, Shah KN. Neonatal dermatology. In: Kang S, Amagai M, Bruckner AL, Enk AH, Margolis DJ, McMichael AJ, et al., editors. Fitzpatrick’s Dermatology. 9th ed. New York: McGraw Hill; 2019. p. 1777–42.
2. Stamatas GN, Tierney NK. Diaper dermatitis: etiology, manifestations, prevention, and management. Pediatr Dermatol. 2014;31(1):1–7.
3. Chirac A, Brzezinski P, Chiriac AE, Foia L, Pinteala T. Autosensitisation (autoeczematisation) reactions in a case of diaper dermatitis candidiasis. Niger Med J. 2014;55(3):274–5.
4. Blume-Peytavi U, Hauser M, Lünnemann L, Stamatas GN, Kottner J, Garcia Bartels N. Prevention of diaper dermatitis in infants—a literature review. Pediatr Dermatol. 2014;31(4):413–29.
5. Odio M, Thaman L. Diapering, diaper technology, and diaper area skin health. Pediatr Dermatol. 2014;31 Suppl 1:9–14.
6. Helmes CT, O’connor R, Sawyer L, Young S. Disposable diaper absorbency: improvements via advanced designs. Clin Pediatr. 2014;53(9 Suppl):145–65.
7. Counts, JL, Helmes CT, Kenneally D, Otts DR. Modern disposable diaper construction: innovations in performance help maintain healthy diapered skin. ClinPediatr. 2014;53(9 suppl):10S–3S.
8. 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.
9. Maesey M. Indonesia: a vulnerable country in the face of climate change. Global Majority E-Journal. 2016;9(3):31–45.
10. Burdall O, Willgres L, Goad N. Neonatal skin care: development in care to maintain neonatal barrier function and prevention of diaper dermatitis. Pediatr Dermatol. 2019;36(1):31–5.
11. Dey S, Kenneally D, Odio M, Hatzopoulos I. Modern diaper performance: construction, materials, and safety review. Int J Dermatol. 2016;55 Suppl 1:18–20.