

Comparative Study between Talcum and Zinc Oxide Cream for the Prevention of Irritant Contact Diaper Dermatitis in Infants

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Background: Baby powder which consists of talcum powder (magnesium silicate) as an active ingredient has been popularly used for prevention of irritant contact diaper dermatitis for a long time because it has water absorbent and friction-decreased properties. There are some case reports of its side effects of pulmonary complication from massive inhalation and the risk of ovarian tumors in adult. However the clinical research on the effectiveness of talcum powder for the prevention of diaper dermatitis has not been investigated.

Objective: To compare the effectiveness between talcum powder with topical zinc oxide cream for the prevention of irritant diaper dermatitis.

Material and Method: Fifty Thai infants at the age of 6-12 months old were randomized. Either topical talcum powder or zinc oxide cream was topically applied to their skin before changing new diapers. The follow-up were conducted at week 0, 2 and 8 to evaluate an occurrence of diaper dermatitis and to collect the median time-to-event data (the duration of disease occurrence). The clinical severity was assessed by using diaper dermatitis severity scoring scale and the side effects were recorded.

Results: The average age of the infants was 8.8 months old. The incidence of irritant contact diaper dermatitis from the talcum group was 4 per 1,000 persons-day (95% confidence interval, 95% CI: 2-7) while the incidence of diaper dermatitis from the zinc oxide group was 2 per 1,000 persons-day (95% CI: 1-5). The median time-to-event outcome of diaper dermatitis for the talcum group was 19 days (interquartile range, IQR: 7-29) which was earlier than that of zinc oxide group, which was 39 days (IQR: 30-59). This showed statistically significant difference ($p = 0.03$, Log rank test). The average of disease duration of the talcum group (mean \pm SD) was 2.7 ± 0.5 days whereas that of the zinc oxide group was 3.7 ± 3.3 days. There is no significant difference between the two groups ($p = 0.34$). Most of the severity of the disease found in both groups is mild. The risk evaluation of diaper dermatitis at week 8, determined by using Cox proportional hazard analysis showed that the talcum group had 5.3 times greater risk than the zinc oxide group (hazard ratio, HR; 5.3, 95% confidence interval, CI: 1.4-20.0), with significant group difference ($p = 0.01$). There was no adverse effect detected on both groups.

Conclusion: Topical zinc oxide cream was better than talcum powder for the prevention of irritant contact diaper dermatitis.

Keywords: Diaper dermatitis, Zinc oxide cream, Talcum powder

J Med Assoc Thai 2016; 99 (Suppl. 8): S1-S6

Full text. e-Journal: <http://www.jmatonline.com>

Diaper dermatitis is a common skin disease during infancy period. Irritant contact diaper dermatitis is the most common cause of diaper dermatitis⁽¹⁾. The clinical manifestation is presented with papules, pustules, patches or erosion on the convex skin area in-contact with diaper including itching and burning

sensation⁽²⁾. The alkaline pH of urine, the fecal enzyme which irritates the skin, the skin overhydration, the skin friction which causes skin maceration are the causes of this disease^(3,4). The common complications of diaper dermatitis are secondary skin infection and side effects from topical steroid used in the treatment^(5,6).

Topical zinc oxide cream is one of the effective topical barrier cream for both treatment and prevention of diaper dermatitis. It has an anti-inflammatory effect, a wound healing promotion⁽⁷⁻¹⁰⁾, and a good barrier effect to protect the skin from irritating agents, skin overhydration and skin friction.

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Baby powder consists of talcum powder or magnesium silicate as an active ingredients. It has been used by consumers for the prevention of diaper dermatitis for a long time in some countries. It has water absorbent and friction-decreased properties. However, the clinical research on the effectiveness of diaper dermatitis prevention has not been investigated.

Material and Method

This is an experimental, prospective randomized controlled trial study. It was done at the Department of Pediatric, Faculty of Medicine, Srinakharinwirot University. Fifty healthy Thai infants between 6 and 12 months of age were enrolled in the study. They all had normal skin on the diaper area. The volunteers who had received topical corticosteroid or anti-inflammatory drugs for 2 weeks, or oral corticosteroid for 4 weeks before the study started were excluded.

The infants were equally randomized to be applied with topical talcum powder or zinc oxide cream (7.5% w/w zinc oxide in cream base) before their diapers were changed. Their parents were given instructions of how to take care of the skin area that was in contact with diaper and 4 disposable diapers were supplied per day. They were followed-up at the 2nd and the 8th week (the end of the study). If the diaper dermatitis occurred, the doctor appointment would be scheduled for clinical evaluation and treatment of the disease. The research outcomes, which include incidence, time-to-event outcome (duration before disease occurrence), hazard ratio, severity of the disease, duration of disease, and parents' satisfaction were evaluated. The severity of the disease was graded with erythema score⁽⁸⁾ as follows; grade 0 (no erythema), grade 1 (mild), grade 2 (moderate), grade 3 (severe), and grade 4 (severe erythema with vesicles or eschar formations). The

comparison of baseline characteristics, duration of disease, and severity of disease were done using t-test and Chi-square. The median time-to-event outcome, the proportion of disease, and the incidence were analyzed using survival analysis and log rank test. The risk factors evaluation (hazard ratio) was analyzed using univariate and multivariate analysis. Descriptive analysis was used for the evaluation of parents' satisfaction. The *p*-value of less than 0.05 was considered as statistically significant difference. This study was approved by the Clinical Ethic Committee of Human Research, Srinakharinwirot University.

Results

All fifty participants completed the protocol. The average age of the infants was 8.8 months. The participants in this study were 29 male (58%) and 21 female infants (42%). There was no statistically difference (*p*>0.05) of the age, gender, caring of diapers area by parents, diaper dermatitis history, parent's education, nutrition, and frequency of defecation per day between the group that used topical talcum powder and the group that used zinc oxide cream (Table 1).

The diaper dermatitis occurrence in the talcum group was 52 percent (*n* = 13) while it was 32 percent (*n* = 8) in the zinc oxide group. The incidence of the disease in the talcum group is 4 per 1,000 persons-day (95% CI: 2-7) while that in the zinc oxide group was 2 per 1,000 persons-day (95% CI: 1-5). The duration of the disease in the talcum group was 2.7±0.5 days whereas that in the zinc oxide group was 3.7±3.3 days. This showed no significant difference (*p* = 0.34).

The median time-to-event outcome was analyzed by using survival analysis. It was found that the median time-to-event outcome in the talcum group was 19 days (IQR: 7-29) while that in the zinc oxide was 39 days (IQR: 30-59). This showed statistically

Table 1. Study demographics

Demographic data	Talcum group (n = 25)	Zinc oxide group (n = 25)	<i>p</i> -value
Gender			
Male, frequency (%)	18 (72)	11 (44)	0.06
Female, frequency (%)	7 (28)	14 (56)	
Mean age, months, ±SD (min-max)	8.7±2.4 (6-12)	8.8±2.1 (6-12)	0.85
Personal history, frequency (%)	3 (12)	1 (4)	0.30
Family history, frequency (%)	4 (16)	4 (16)	1.00
Drug allergy, frequency (%)	1 (4)	-	0.31
Full vaccination history, frequency (%)	25 (100)	25 (100)	1.00

significant difference ($p = 0.03$). Regarding the proportion of disease at the 2nd week, it was 42% in the talcum group and 11% in the zinc oxide group. At the end of the study, the proportion was 92 percent in the talcum group and 72 percent in the zinc oxide group (Fig. 1).

The risk factors of diaper dermatitis were analyzed. The only risk factor that caused diaper dermatitis occurrence was the topical agent used for disease prevention ($p = 0.04$). Moreover, it was found that the talcum group had 5.3 times greater risk of diaper dermatitis than the zinc oxide group (hazard ratio, HR = 5.3, 95% CI: 1.4-20.0). The statistically significant difference was $p = 0.01$ (Table 2).

The severity of disease is mostly mild. There was no significant difference between the talcum and the zinc oxide group ($p = 0.63$, Table 3). There was no adverse effect found in this study.

At the end of the study, the parents' satisfaction was evaluated. It was found that the parents' satisfaction of both groups were good, with no significant difference ($p = 0.55$).

Discussion

The prevention of diaper dermatitis consisted

of topical barrier cream application and the avoidance of aggravating factors such as the selection and use of ultra-absorbent disposable diapers, the number of diapers used per day. Many topical products such as petrolatum ointment, zinc oxide cream, dexpanthenol ointment are used for the prevention of irritant contact diaper dermatitis. Zinc oxide cream is one of the

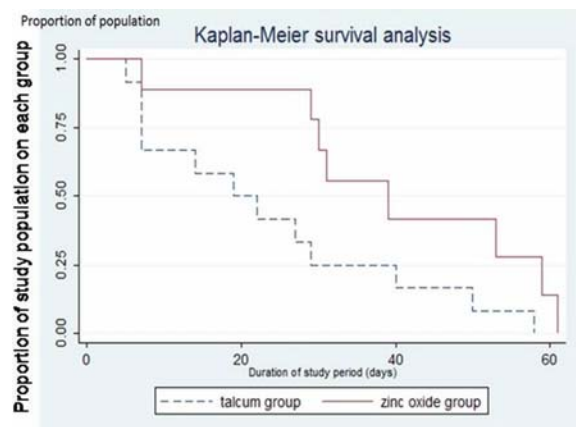


Fig. 1 Comparison of the median time-to-event between the talcum and the zinc oxide group.

Table 2. Comparison of diaper dermatitis risk factors using univariate analysis

Risk factors of diaper dermatitis	Univariate* HR, 95% CI	p-value
Talcum: zinc oxide	5.3 (1.4-20.0)	0.01
Frequency of application (≥ 4 /day: < 4 /day)	0.4 (0.1-1.9)	0.27
Frequency of diaper changing (≥ 4 /day: < 4 /day)	1.2 (0.3-4.4)	0.26
Mother education (≥ 12 years: < 12 years)	1.2 (0-4.4)	0.75
Nutrition (powdered milk: breast feeding)	1.2 (0-3.4)	0.76
History of diaper dermatitis (yes: no)	1.3 (0.5-3.6)	0.57

HR = Hazard ratio, 95% CI = 95% confidence interval

* Cox proportional hazard model, Breslow test

Table 3. Comparison of the severity of diaper dermatitis between the talcum and the zinc oxide group

Severity of disease, n (%)	Talcum group (n = 13)	Zinc oxide group (n = 8)	p-value
Slightly	3 (23.1)	3 (37.5)	0.63
Mild	5 (38.4)	2 (25)	
Mild to moderate	3 (23.1)	1 (12.5)	
Moderate	1 (7.7)	2 (25)	
Moderate to severe	1 (7.7)	-	
Severe	-	-	

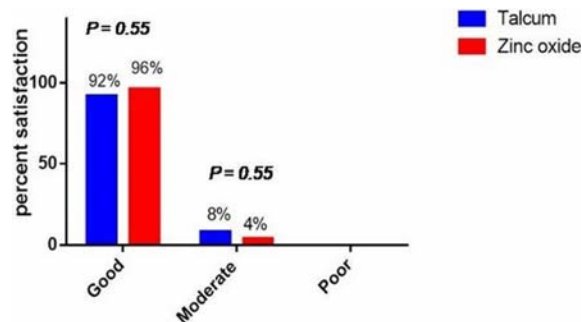


Fig. 2 Parents' satisfaction between the talcum and the zinc oxide group.

standard preventions⁽⁹⁾. It has been demonstrated by many previous studies that it is effective for the prevention of diaper dermatitis. In the clinical trial of Baldwin et al⁽⁸⁾, the severity of diaper dermatitis in the zinc oxide treated group is compared with that in the control group. By the end of the 4th week, it was shown that zinc oxide group has less severity of disease than that of the control group. Regarding baby powder or talcum powder, it has been used for this purpose in some countries including Thailand. Even though, there are some reports demonstrating that massive inhalation of talcum powder has some side effects such as pulmonary complication and higher risk of ovarian tumors in adults⁽¹¹⁻¹⁴⁾. Moreover, it could produce ablative skin lesions in the moist flexural areas by forming clumps of larger powder particles. However, the clinical study of the effectiveness of the talcum powder in prevention of diaper dermatitis has never been conducted. Hence, to the best of our knowledge from literature reviews, this is the first clinical trial.

From the results of this study, it was found that zinc oxide cream application has greater effectiveness for the prevention of irritant contact diaper dermatitis than talcum powder application, with statistically significant difference (a lower incidence, a longer median time-to-event outcome, and hazard ratio). However, there is no significant difference in terms of severity reduction and duration of disease. The talcum powder group has 5.3 times greater risk of disease occurrence than that of zinc oxide group.

The limitation of this study is a lack of objective measurements such as the erythema index by Mexameter, trans-epidermal water loss by Tewameter.

Conclusion

The topical zinc oxide cream was better than

talcum powder for the prevention of irritant contact diaper dermatitis in infants.

What is already known on this topic?

The topical zinc oxide cream is used for standard prevention of diaper dermatitis in infants. However, in Thailand, baby powder or talcum powder is more popularly used. There is no clinical research to support the effectiveness of talcum powder for diaper dermatitis prevention while there are some reports that show the side effects from talcum powder.

What this study adds?

The topical zinc oxide cream has been proven to have better effectiveness in the diaper dermatitis prevention in infants than talcum powder.

Acknowledgements

We would like to acknowledge Faculty of Medicine, Srinakharinwirot University for grant supporting, and Suchada Boon-itt, former lecturer, Department of Western Languages, Faculty of Humanities, Srinakharinwirot University for the grammatical correction.

Potential conflicts of interest

None.

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การศึกษาเปรียบเทียบประสิทธิผลระหว่างแป้งทัลคัมและซิงค์ออกไซด์ครีมในการป้องกันผื่นผ้าอ้อมในเด็ก

สุธิดา ศิริพรพาณิชย์, ศิริลักษณ์ อรุณจิตต์, เทพ เฉลิมชัย, อรุชาตรี ศิริโชติ, มนตรี อุดมเพทายกุล

ภูมิหลัง: แป้งทัลคัมเป็นส่วนประกอบของทัลคัม (แมกนีเซียม ซิลิเกต) ที่เป็นสารประกอบหลักยังเป็นที่ยอมรับกันมาช้านานในการป้องกันโรคผื่นผ้าอ้อมในเด็กทารก โดยมีคุณสมบัติสำคัญในการดูดซับความชื้นและสามารถลดการเสียดสีได้ มีรายงานว่าทัลคัมทำให้เกิดผลข้างเคียงต่อระบบทางเดินหายใจจากการสูดดมในปริมาณมากและทำให้เกิดเนื้องอกในรังไข่ในผู้ใหญ่ได้ อย่างไรก็ตามยังไม่มีข้อมูลแน่ชัดว่างานวิจัยทางคลินิก เพื่อศึกษาถึงประสิทธิผลของแป้งทัลคัมในการป้องกันโรคผื่นผ้าอ้อมอีกด้วย

วัตถุประสงค์: เพื่อศึกษาเปรียบเทียบประสิทธิผลด้านป้องกันการเกิดผื่นผ้าอ้อมของแป้งทัลคัมกับการใช้ครีมทาเฉพาะที่ที่มีส่วนผสมของซิงค์ออกไซด์ วัตถุประสงค์และวิธีการ: อาสาสมัครเด็กจำนวน 50 คนอายุระหว่าง 6-12 เดือน มีสุขภาพแข็งแรงแบ่งกลุ่มโดยวิธีการสุ่มเลือกเป็นสองกลุ่มเท่ากัน ให้คำแนะนำในการดูแลผื่นผ้าอ้อมและทาสารทดสอบ เพื่อป้องกันผื่นโดยกลุ่มแรกได้แป้งทัลคัมและกลุ่มที่สองได้รับครีมที่มีส่วนผสมของซิงค์ออกไซด์ ทาทุกครั้งหลังเปลี่ยนและก่อนใส่ผ้าอ้อมใหม่ ประเมินการติดตามค่านับถือการเกิดผื่นผ้าอ้อม ระยะเวลาตั้งแต่เริ่มต้นจนเกิดผื่น โดยการติดตามที่ระยะเวลาตอนเริ่มต้นการศึกษา 2 และ 8 สัปดาห์ และประเมินความรุนแรงของผื่นและผลข้างเคียงที่อาจเกิดขึ้น

ผลการศึกษา: อาสาสมัครเด็กที่เข้าร่วมการศึกษาทั้งสิ้น 50 คน มีอายุเฉลี่ย 8.8 เดือน (ระหว่าง 6-12 เดือน) พบอุบัติการณ์การเกิดผื่นผ้าอ้อมเท่ากับ 4 คน ต่อ 1,000 คน-วัน (confidence interval, 95% CI: 2-7) ในกลุ่มที่ได้แป้งทัลคัม ซึ่งน้อยกว่าเมื่อเทียบกับกลุ่มที่ได้ครีม ซึ่งมีส่วนผสมของซิงค์ออกไซด์ที่พบ 2 คนต่อ 1,000 คน-วัน (95% CI: 1-5) ค่าเฉลี่ยระยะเวลาตั้งแต่เริ่มต้นจนเกิดโรค พบว่ากลุ่มแป้งทัลคัมเท่ากับ 19 วัน (interquartile range, IQR: 7-29) ซึ่งเกิดขึ้นเร็วกว่าเมื่อเปรียบเทียบกับกลุ่มที่ใช้ครีมทาเฉพาะที่ที่มีส่วนผสมของซิงค์ออกไซด์ที่เท่ากับ 39 วัน (IQR: 30-59) โดยแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p = 0.03$, Log rank test) ระยะเวลาการเป็นโรคผื่นผ้าอ้อมเฉลี่ยในกลุ่มแป้งทัลคัมเท่ากับ 2.7 ± 0.5 วัน และครีมทาเฉพาะที่ มีส่วนผสมของซิงค์ออกไซด์เท่ากับ 3.7 ± 3.3 วัน ซึ่งไม่พบความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p = 0.34$) พบว่าส่วนใหญ่มีอาการของผื่นระดับรุนแรงน้อยในทั้งสองกลุ่ม จากกราฟวิเคราะห์ด้านความเสี่ยงการเกิดโรคที่ระยะเวลา 8 สัปดาห์ โดยวิธีวิเคราะห์แบบ Cox proportional hazard พบว่ากลุ่มที่ใช้แป้งทัลคัมมีความเสี่ยงต่อการเกิดโรคผื่นผ้าอ้อมเป็น 5.3 เท่า เมื่อเทียบกับกลุ่มที่ได้ครีมที่มีส่วนผสมของซิงค์ออกไซด์ (Hazard ratio, HR: 5.3, 95% CI: 1.4-20) โดยมีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p = 0.01$) และไม่พบผลข้างเคียงของทั้งสองกลุ่ม

สรุป: การใช้ครีมที่มีส่วนผสมของซิงค์ออกไซด์ดีกว่าการใช้แป้งทัลคัมในการป้องกันผื่นผ้าอ้อม
