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Evaluation of a 5% dexpanthenol-containing ointment for the treatment of infant irritant diaper dermatitis through the lens of the caregiver—A real-world data observational study

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Abstract

Background and Aims: Irritant diaper dermatitis (IDD) is very common in infants and usually managed by the caregiver. Dexpanthenol-containing ointment (DCO) is a decades-long established product that has demonstrated efficacy and tolerability in the treatment and prevention of infant IDD in controlled clinical settings. The aim of this study was to evaluate the effectiveness of DCO in the treatment of infant IDD from the perspective of the caregiver by collecting data not explored in clinical trials, such as infant quality of life and the speed of action.

Methods: A retrospective observational real-world data (RWD) study was conducted with French adult caregivers who had used a DCO to treat IDD in their infants within the past 6 months and consented to participate to the study completed a web-based survey answering questions regarding the severity of their infants' symptoms (intensity/extent of redness and discomfort, rated using Likert scales) before and after DCO application. The speed of onset of symptom relief and product acceptability were also collected.

Results: A total of 500 caregivers of 564 infants completed the survey. Of these, 80% reported that DCO visibly treats IDD. In terms of speed of action, 83% declared that the first signs of symptom relief appeared after 1 day of application and 78% reported full symptom resolution within 2 days of application. Additionally, ≥77% of caregivers agreed that DCO provided overnight relief from the discomfort caused by IDD and reduced sleep disturbance in their children. Finally, 85% of caregivers declared being satisfied with the product overall and considered the product pleasant to use.

Conclusion: This evidence from caregivers' experience confirms that DCO can be considered an adequate medication to self-manage IDD episode as it provides rapid relief of the signs and symptoms of inflammation, while by being pleasant to be use.

KEYWORDS

dexpanthenol, diaper dermatitis, quality of life, real-world data, selfcare

1 | INTRODUCTION

Irritant diaper dermatitis (IDD), also known as diaper rash, is an inflammatory skin reaction associated with the wearing of diapers.[1] The most commonly affected skin sites include the buttock, perianal, genital, and intertriginous areas.[2] There are many contributory factors, but the main cause is prolonged contact of the skin with irritants in urine and feces.[2,3] These irritants, in turn, disrupt the structure of the skin, leading to local inflammation.[3,4]

IDD is characterized by reddening or scaling of the skin, which if untreated can progress to exudative or ulcerated lesions.[5–7] The condition can cause considerable discomfort to the baby, and can be distressing both to the infant, negatively impacting sleep and behavior,[8,9] and to the caregiver.[10,11] In most cases, IDD is managed by the caregiver rather than referred to a physician[1,6,12]; hence, estimating the incidence of IDD is difficult. Published incidence rates range from 50% to ~70%, but it is thought that almost every infant will experience at least one episode of IDD at some time, with multiple episodes occurring in many infants.[2,5,6,13,14] The condition peaks at around 9–12 months of age.[5] Although moderate to severe IDD seems to have been more common in the past, nowadays the condition is usually mild, with reported incidences of up to 20%–30% for moderate IDD and 5%–9% for severe IDD.[5,6,15] Treatment and prevention strategies for infant IDD include the regular application of a topical protective barrier product.[3,7,16] Standards for an ideal barrier product for the treatment and prevention of infant IDD, established by expert dermatologists and pediatricians,[3] include proven clinical efficacy and safety in an infant population, protection of the skin barrier, maintenance of optimum hydration, and the inclusion of no unnecessary, potentially toxic or sensitizing ingredients.[3,7]

Dexpanthenol is a constituent of many topical ointments and has long been used as a treatment for individuals with skin complaints.[17] When applied to the skin, dexpanthenol is rapidly absorbed and metabolized to pantothenic acid.[18] Pantothenic acid is a constituent of coenzyme A, which catalyzes the synthesis of key components of the lipid layers of the skin that play a role in maintaining the skin's barrier function.[17,19] Topical dexpanthenol-containing products have been shown to maintain and repair the skin barrier function, supporting the healing of skin and reducing inflammation, and to maintain hydration of the skin's outer layer, decreasing transepidermal water loss.[4,19–22]

Ointment preparations are water-in-oil emulsions with high lipid content (over 50% generally) and are the preferred galenic formulation for IDD management. Ointment preparations provide a durable barrier that is effective yet "breathable," helping to maintain skin hydration while reducing diaper friction.[3,8,23] The efficacy and tolerability of Dexpanthenol-containing ointment (DCO) have been demonstrated in controlled clinical settings for both treatment and prevention of infant IDD.[23–27] There remains, however, a lack of understanding of the caregivers' perspective about how they self-manage the condition in a real-world setting.

The aim of this real-world data (RWD) study was to evaluate the effectiveness of a DCO (Bepanthen® pommade; Bayer HealthCare) in the treatment of infant IDD from the perspective of the caregiver, collecting data not explored in clinical trials, such as infant quality of life and the speed of action.

2 | MATERIALS AND METHODS

2.1 | Study design

To achieve the study aim, it was decided to conduct an RWD retrospective observational study involving exclusively adult caregivers of infants with IDD. The real-world study setting has been considered as the most appropriate approach to explore the product effectiveness under normal use conditions and collecting user insights on speed of action as well as quality of life aspects. Indeed, IDD is usually managed by caregivers[1,6,12] themselves without involvement of a physician. Due to their daily contact and exposure, caregivers are ideally qualified to detect and monitor the evolution of an IDD episode, to judge on the product treatment effect, and to assess the overall health of their child. The retrospective approach was chosen as being the more conservative generating less bias than a prospective approach.

Participants were recruited from a consumer panel previously profiled for use of 5% dexpanthenol ointment, who had indicated that they were willing to take part in online surveys of this type. Participants were informed electronically about the study, and those consenting to take part were screened for eligibility using an online questionnaire. Recruited participants then completed the full online questionnaire via a computer-aided web quantitative interview (maximum duration 20 min), selecting answers to the questions posed from lists provided. Recruitment to the study was conducted by an independent agency, IQVIA Inc.

This study involved no randomization of participants or intervention, no provision of the product to the participant, no healthcare professional input, and no consultation of medical records; hence, ethical approval or regulatory submission was not required.

The selected DCO (Bepanthen® pommade; Bayer HealthCare) is a well-established DCO product on the French market. The product is registered since 1995 as a medicinal product available over the counter only in pharmacies and indicated for the treatment of infant IDD.

2.2 | Survey development

Survey questions were developed by Bayer Consumer Care AG and IQVIA. The final version comprised 36 questions in total. Caregivers could provide information for more than one infant if they took care of multiple infants.

After providing general information, caregivers assessed overall IDD severity using lay person-friendly pictures showing degrees of

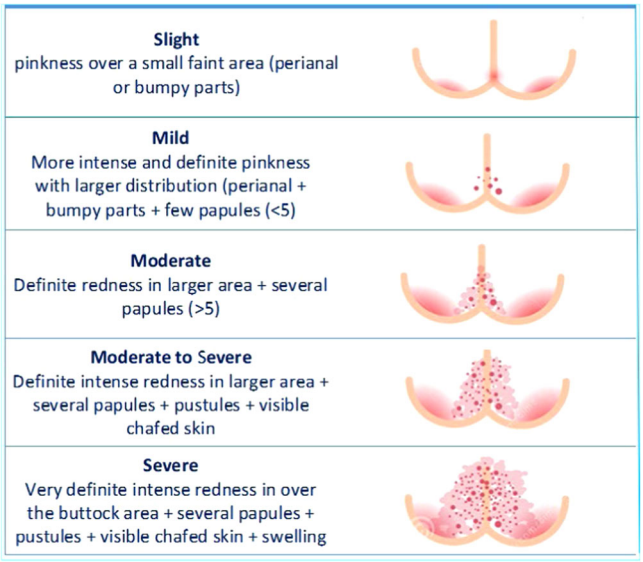

FIGURE 1 Different degrees of irritant diaper dermatitis.

IDD severity from "slight" to "severe" (Figure 1) and answered questions regarding the severity of their infants' symptoms before/after application of the product.

Caregivers rated the severity of IDD symptoms (intensity of redness, extent of the redness, and apparent discomfort) separately. Redness intensity was assessed using a six-point Likert scale (1 = no redness at all; 2 = slight redness/pinkness; 3 = slightly less than moderate redness; 4 = moderate redness; 5 = slightly more than moderate redness; 6 = severe redness). The extent of redness was assessed using a seven-point scale (1 = no lesion; 2 = only perianal; 3 = only on the bumpy area; 4 = on the bumpy area AND perianal area; 5 = over the buttock area; 6 = all over the diaper area/genital area; 7 = beyond the diaper area). Apparent discomfort was assessed using a six-point Likert scale (1 = no discomfort; 2 = slight discomfort; 3 = slightly less than moderate discomfort; 4 = moderate discomfort; 5 = slightly more than moderate discomfort; 6 = severe discomfort).

A combination score was created by adding the scores for the three symptoms (intensity of redness, extent of redness, and apparent discomfort). This combination score describes the overall severity of IDD, with 0–3 = absence of IDD; 4–6 = slight IDD; 7–9 = mild IDD; 10–12 = moderate IDD; 13–15 = moderate to severe IDD; 16–18 = severe IDD. To facilitate this, the extent of redness scale was adapted to combine the scores of 6 (all over diaper area/genital area) and 7 (beyond diaper area) (both indicative of severe IDD).

Speed of onset of symptom relief, effect of the product on infants' overnight relief from discomfort and sleep disturbance, and overall caregiver satisfaction with the product were assessed using seven-point scales. Answers to three options—slightly agree/satisfied, agree/satisfied, and strongly agree/satisfied—were combined and considered to represent positive feedback. A post hoc analysis compared the resulting percentages to an arbitrarily defined threshold value of 70% to provide guidance on the statistical significance of the responses.

The study questionnaire was not formally validated but reviewed before use by project stakeholders (employees of Bayer Consumer Care AG and of IQVIA). Content, order, and language of the questions were amended based on comments received to make the questionnaire as comprehensible to the intended audience as possible.

Although the survey aimed primarily to collect data regarding the effectiveness of DCO in the treatment of infant IDD, it was possible for participants to declare any adverse events experienced with the product via the Bayer website dedicated to spontaneous adverse event reporting.

2.3 | Survey population

For inclusion in the study, participants had to be aged >18 years, be caring for one or more infant aged 0–24 months, have used the selected DCO within the previous 6 months, be able to read and understand the language (French) of the online survey, and agree that the data collected could be used for research and marketing purposes. Participants had to have used the selected DCO for the treatment (not for prevention only) of IDD.

Due to its real-world nature, no exclusion criteria were specified.

2.4 | Data collection and analysis

The survey was conducted in France between January and March 2020. Answers to the online survey were pseudo-anonymized and forwarded electronically directly to IQVIA, which then carried out the data management and aggregated statistical analyses required.

2.5 | Sample size and power

The sample size calculation was based on that usually used to estimate sample sizes for a marketing survey involving a large population. Assuming an error margin of 5%, an SD of 0.5, and a confidence level of 95%, a sample size of approximately 400 participants would have been sufficient for a study of this type. However, assuming an attrition rate of approximately 25% for individuals not fully completing the questionnaire, the estimated sample size was 500. Due to the real-world nature of the study, however, no limit was imposed on the total number of participants who could be enrolled.

2.6 | Statistical methods

Statistics were descriptive only. Data are provided as numbers and percentages of respondents.

For the post hoc analysis, a binomial exact test was used to ensure whether the proportion of top three boxes was greater than 70% (the arbitrarily defined threshold for relevance) at a 95%

confidence interval. This analysis was performed using Microsoft Excel version 16.0 for Office 365.

3 | RESULTS

From a panel comprising 31,490 users of the selected DCO, 500 consented to participate, met the inclusion criteria, and completed the survey. These participants were caring for a total of 564 infants (average of one infant per caregiver) and derived from a wide number of locations across mainland France. A majority (481/500; 96%) were the parent of the infant they were caring for. Just over half of the infants being cared for were male (286/564; 51%) and most (157/564; 27.8%) were aged between 21 and 24 months (Table 1). Before application of the product, most caregivers rated their infants' diaper rash as either mild (n = 169/564; 30%), moderate (169/564; 30%), or moderate to severe (73/564; 13%) in severity. Only 11/564 (2%) rated their babies' IDD as severe (Table 1). The distribution pattern was slightly different when applying the combination score, with a greater proportion of moderate to severe (135/500; 27%) and severe (39/500; 7%) IDD (Table 2).

TABLE 1 Demographics data regarding caregivers and infant profiles (n = 564)

Parameter	n (proportion %)
Caregivers	n = 500
Relationship to infant	
Mother	357 (71)
Father	124 (25%)
Aunt	10 (2%)
Uncle	3 (<1%)
Grandmother	1 (<1%)
Grandfather	1 (<1%)
Other	4 (<1%)
Infants	n = 564
Gender (male/female)	286 (51%)/278 (49%)
Age group (months)	
0–3	60 (10.6%)
3–6	68 (12.1%)
6–9	64 (11.3%)
9–12	67 (11.9%)
12–15	69 (12.2%)
15–18	79 (14.0%)
21–24	157 (27.8%)
IDD severity before product application based on visual assessment	n = 564
Slight IDD	90 (16%)
Mild IDD	169 (30%)
Moderate IDD	169 (30%)
Moderate to severe IDD	73 (13%)
Severe IDD	11 (2%)
Missing value	52 (9%)

Abbreviation: IDD, irritant diaper dermatitis.

3.1 | Impact of DCO on symptom relief and the onset of action

A total of 415/500 (83%) of caregivers reported the first signs of symptom relief 1 day after the first application of DCO, and 490/500 (98%) reported the first signs of symptom relief within 2–3 days (Figure 2A). A total of 390/500 (78%) of caregivers indicated that IDD symptoms disappeared/resolved within 2 days of application (Figure 2B). Overall, 395/500 (79%) of caregivers reported that DCO visibly treated diaper rash (Figure 3).

3.2 | Impact of DCO on overnight relief of discomfort and sleep disturbance

A total of 400/500 (80%) caregivers agreed that their infants experienced overnight relief from the discomfort caused by diaper rash with DCO (Figure 3). Additionally, application of DCO before bedtime was reported by 385/500 (77%) of caregivers to reduce the level of sleep disturbance experienced by babies with diaper rash (Figure 3). These percentages were significantly higher than 70% at a 95% confidence interval ($p \leq 0.001$; Figure 3).

3.3 | Impact of DCO on symptoms of IDD (intensity/extent of redness, apparent discomfort)

Combining caregivers' assessments of skin redness/extent and overall discomfort allowed for the calculation of a combined IDD score before and after product application, and therefore a conclusion on the overall change in IDD (Table 2). A positive evolution of symptoms was noticed by 383/500 (77%) caregivers as early as 1 day after product application; no positive evolution was observed in 117/500 (23%) of cases (Table 2). The symptom-based combination score results confirmed the percentage of caregivers who reported the first signs of symptom relief 1 day after first application of DCO (415/500; 83%) (Figure 2A), and thus the validity of the observation.

3.4 | Caregiver satisfaction

A total of 425 (85%) caregivers were satisfied overall with the product and 395/500 (79%) found it easy to apply (Figure 4). Similar results were obtained on questions regarding intent to repurchase

(440/500; 88%), recommending the product (425/500; 85%), and product value for money (415/500; 83%).

The percentages of respondents to these questions were significantly higher than 70% at a 95% confidence interval ($p \leq 0.001$; Figure 3).

TABLE 2 IDD combined score: proportion and evolution based on caregivers' assessment ($n = 500$)

	n (proportion %)
IDD severity before product application calculated via combined score approach	
Absence of IDD (score 0–3)	5 (1)
Slight IDD (score 4–6)	28 (6)
Mild IDD (score 7–9)	135 (27)
Moderate IDD (score 10–12)	156 (31)
Moderate to severe IDD (score 13–15)	137 (27)
Severe IDD (score 16–18)	39 (7)
IDD evolution after 1 day of product application using the combined score[a]	
Overall symptom improvement	383 (76.6)
Absence of symptom improvement	117 (23.4)

Abbreviation: IDD, irritant diaper dermatitis.

[a]A lower combined score *after* product application than *before* product application was considered as IDD improvement.

3.5 | Adverse events

During the period of the study, one adverse event—application site discomfort—was reported via the Bayer website from a region in France.

Application site discomfort is rarely observed with DCO products, as with any other topical IDD product.

4 | DISCUSSION

Most caregivers (76%) in this study considered the severity of their infants' IDD to be slight to moderate; moderate to severe and severe symptoms were reported by 13% and 2% of caregivers, respectively. Interestingly, the percentage of moderate-to-severe and severe IDD were higher (27% and 7%, respectively) with the combined score approach, which might indicate the importance of the apparent discomfort aspect in the caregivers' perception of IDD. Although it is difficult to draw comparisons due to the different severity scales used, these percentages appear to be higher than those in some early published reports,[5,15] but are in line with the results of another recent RWD study,[28] which may suggest that the incidence of moderate-to-severe IDD may be higher than generally recognized. Alternatively, this discrepancy may reflect the fact that, in a real-world setting, the caregiver may exhibit emotional bias that might, in

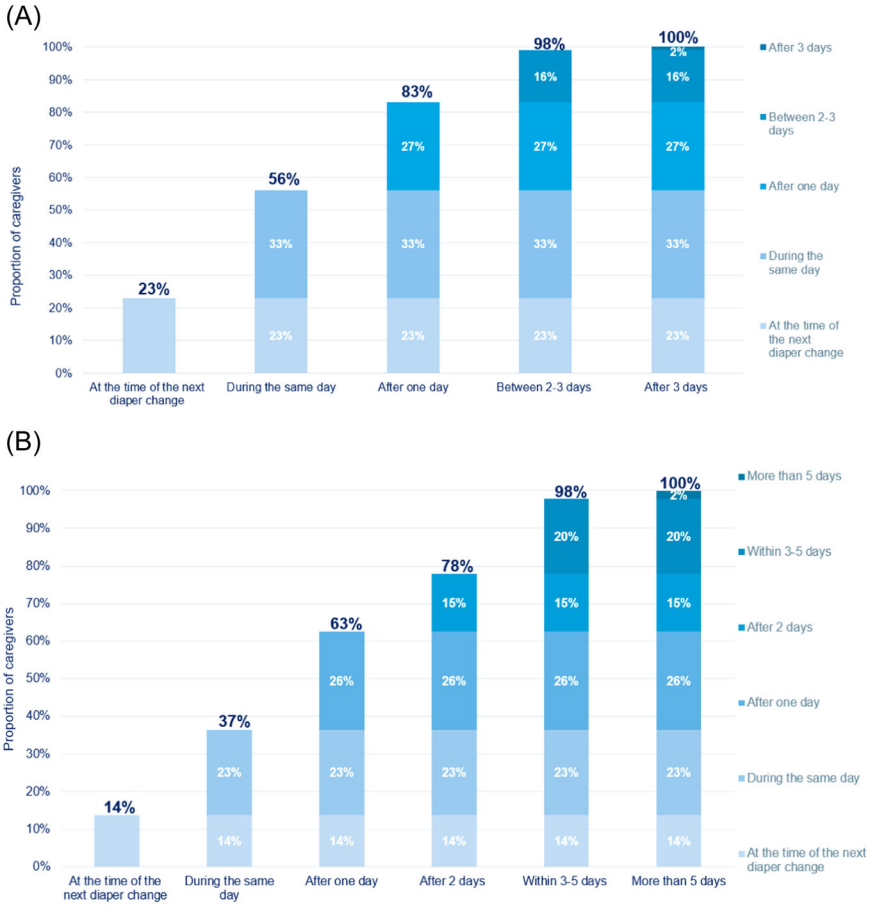

FIGURE 2 (A) Time to observation of first symptom relief after product application ($n = 500$). Bars denote caregivers' cumulative assessment of symptom relief over time. (B) Time to observation of complete symptom resolution after product application ($n = 500$). Bars denote caregivers' cumulative assessment of complete symptom resolution over time.

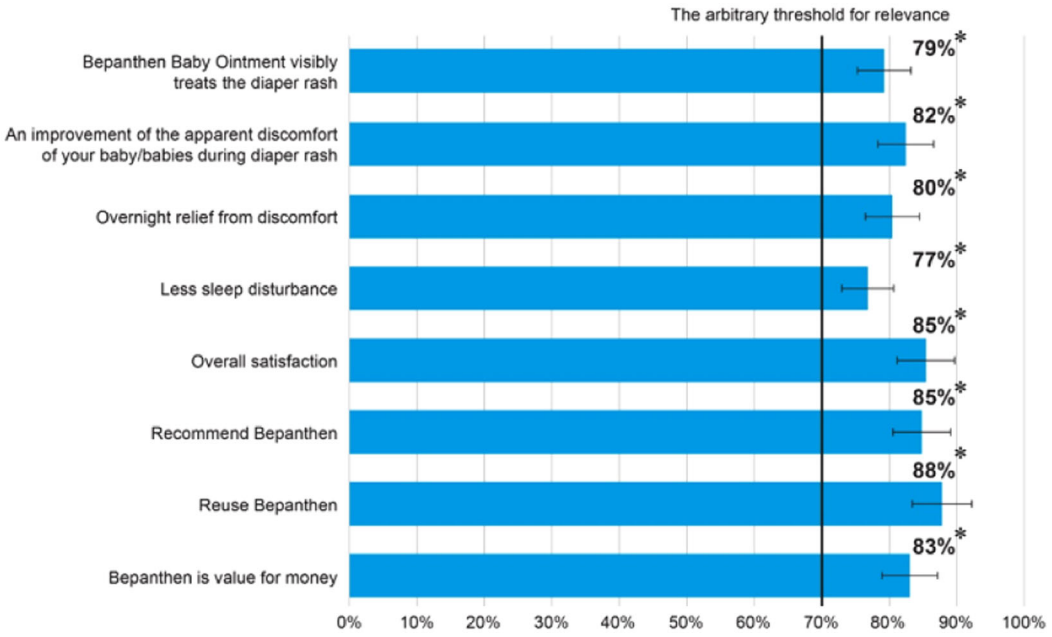

FIGURE 3 Proportion of positive feedback (combined options: slightly agree/satisfied, agree/satisfied, strongly agree/satisfied), $n = 500$, 95% CI. *Binomial exact test was used to ensure whether the proportion of top 3 boxes was greater than 70% at a confidence interval ($p \leq 0.001$).

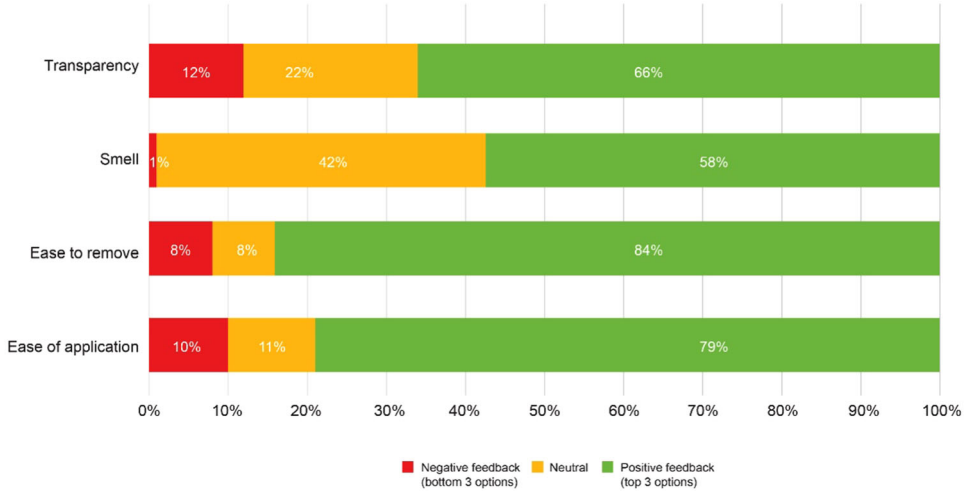

FIGURE 4 Caregivers' ratings of product attributes ($n = 500$)

the absence of medical knowledge, result in an overestimation of IDD severity. Or it may stress the importance of quality of life when assessing IDD severity.

The usefulness of an overall IDD severity score in the assessment of IDD prevention and treatment strategies has been proposed elsewhere.[29]

Speed of action is an important feature for an IDD treatment from the caregiver's perspective, and one that has yet to be investigated in clinical trials. Almost all (490/500; 98%) of caregivers in the present study reported the first signs of symptom relief within 2–3 days of product application, with over (375/500; 75%) indicating that symptoms disappeared/resolved after 2 days.

Speed of action is also an important feature of an IDD treatment from the physician's perspective. Although IDD is the most common cause of rash in the diaper area, if the erythema fails to respond promptly to treatment this may be an indication that a cause other than IDD should be sought.[30]

In previously published clinical trials, conducted under controlled conditions, DCO has been shown to reduce symptoms of skin redness and extent in infants with IDD.[23,26] The results of the present study confirm these findings, with caregivers reporting reductions in redness and the extent of redness within 1 day of application of DCO. However, this RWD study allowed further exploration of important aspects beyond those usually

examined in clinical trials, particularly infant discomfort and distress.

Discomfort and distress are common among infants with IDD,[8–11] and in our study, caregivers reported improvements in relief of overnight discomfort, sleep disturbance, and overall discomfort following the application of the product.

One of the main strengths of this study is that the information collected on the use of the diaper care treatment was obtained from a relevant source: the caregivers of infants with IDD. IDD is largely managed by caregivers without reference to medical personnel[1,6,12] and, in France, is considered a condition for self-medication; such medications do not require medical consultation and prescription.[31,32] Caregivers of infants with IDD are ideally placed to detect and monitor any impact of an IDD treatment, not only on their infants' visible symptoms of IDD (skin redness/extent) but also on their infants' quality of life.[33] They are also more likely to notice changes in their babies' behavior or demeanor that would not be taken into account by physicians or in a formal study, and parent-proxy reporting plays an important role in overcoming challenges associated with assessing the subjective experience of young children.[34] A real-world setting was therefore considered a most appropriate type of study for collecting these data.

This study has some limitations. Since the study was conducted without healthcare professional involvement, the diagnosis of IDD relied exclusively on the participants' evaluation. Further differential diagnosis was not done and any observed rash in the diaper area was considered an IDD. IDD is referenced in scientific literature as the most common etiology of skin eruption/rash seen in the diaper area, other forms of diaper dermatosis are rarer.

Retrospective data collected via a questionnaire cannot be monitored, and there is currently little guidance on the conduct of such studies; however, the same principles as for a consumer survey apply. One of them is the time constraint which limits the number of questions. With a time limit of 20 min, some aspects had to be superficially investigated like pharmacist recommendation and caregiver's skincare routine during the IDD episode. Information on a potential joint use of other topical products (e.g., cleansers, wipes) is lacking, which may raise the question whether the observed IDD improvement is solely imputable to the DCO. However, it can be assumed that these types of daily care products are used on a daily basis and not specifically for the IDD episode. Caregivers tend to limit the number of product uses on infant's skin, and the additional use of other topical protective barrier products is judged as unlikely. Although retrospective data are not as robust as real-time reporting of clinical endpoints in a clinical trial, and may be affected by recall bias,[35] the impact of this limitation was reduced by the fact that caregivers had to have used the selected DCO in the 6 months before the study. Additionally, as negative outcomes tend to have more of an impact than positive ones,[36] the use of a conservative, retrospective approach, together with the fact that caregivers received no incentives to participate, helped to ensure we obtained unbiased feedback from the participants.

Although the questionnaire has not been formally validated, the study followed a similar approach to that used in another RWD study in this disease area,[37] which also used Likert scales to assess skin redness/extent and perceived discomfort. This allowed us to confirm the validity of our findings in a post hoc analysis comparing overall caregivers' assessments with data collected on the three IDD symptoms. The outcome of this post hoc analysis was consistent with the study results and confirms the results for product efficacy and the scientific credibility of the RWD approach.

The internet has facilitated access of the general public to medical information, consequences of which include a better engagement of people in their health care. This, in parallel with the growing use of social media, has resulted in an increased willingness of individuals to share personal health data, knowledge, and experiences through digital platforms. A real-world observational study with digital recruitment is well placed to use digital technology to capture emerging behavioral patterns. Although this novel methodology has some weaknesses, such as the lack of monitoring and guidelines, we consider it appropriate for the investigation of self-medication treatments (for which efficacy and safety have been properly evaluated), with particular usefulness for the assessment of quality-of-life issues.

5 | CONCLUSION

This RWD study is one of the first digitally driven questionnaires which allowed to reach a large number of caregivers who have used a DCO within the past 6 months in multiple regions of France. The evidence from caregivers' experience confirms that regular DCO application leads to IDD symptoms resolution as 490/500 (98%) of caregivers indicated that IDD symptoms disappeared/resolved within 5 days of application. In addition, this RWD provides valuable new information as regards to the speed of action of DCO products with 415/500 (83%) of caregivers reporting the first signs of symptom relief at 1 day after the first application of DCO, and as regards to quality of life with the positive effect of the DCO use on infants' skin discomfort and sleeping pattern.

This evidence from caregivers' experience confirms that DCO can be considered an adequate medication to self-manage IDD episode as it provides rapid relief of the signs and symptoms of inflammation, while by being pleasant to be use.

AUTHOR CONTRIBUTIONS

Erwan Peltier: Conceptualization; methodology; visualization; writing – review & editing. **Raffaella de Salvo**: Conceptualization; methodology; project administration; writing – review & editing. **Andreas Ehret**: Conceptualization; methodology; project administration; writing – review & editing. **Sonja Trapp**: Conceptualization; methodology; writing – review & editing. **Didier Lakomsky**: Conceptualization; methodology; writing – review & editing. **Maged A. El Shazly**: Conceptualization; methodology; visualization; writing – review & editing.

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CONFLICTS OF INTEREST

Erwan Peltier, Raffaella de Salvo, Andreas Ehret, Maged A. El Shazly, and Sonja Trapp are employees of Bayer Consumer Care AG, Switzerland. Maged A. El Shazly was an employee of Bayer Consumer Care AG, Switzerland at the time of the study and he is now an employee of Bayer Pakistan Pvt Ltd. Didier Lakomsky is an employee of Bayer Health Care Division Consumer Care, France

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

TRANSPARENCY STATEMENT

The lead author (Erwan Peltier) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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