Evaluation of Off-Label Use of Sucralfate Suspension for the Treatment of Irritant Contact Dermatitis in Patients with Stoma

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Abstract

Irritant Contact Dermatitis (ICD) is a common complication among stoma patients. Sucralfate has been shown to form a protective barrier over irritated skin and stimulate the production of growth factors such as Fibroblast Growth Factor (FGF) and Epidermal Growth Factor (EGF), thereby accelerating tissue regeneration. In Indonesia, sucralfate suspension is frequently used off-label as a topical agent for ICD management. This study aimed to evaluate the effectiveness of topical sucralfate suspension + NaCl 0.9% therapy compared with NaCl 0.9% only in improving clinical outcomes in stoma patients with ICD. A retrospective study was conducted using medical records from RSPAU dr. Suhardi Hardjolukito, Yogyakarta, between March 2023 and March 2025. Among 66 stoma patients identified, 50 met the inclusion criteria (25 received sucralfate + NaCl 0.9% and 25 received NaCl 0.9% only). Clinical outcomes included changes in skin irritation and pain reduction (ΔVAS) from day 1 to day 3. Additional variables such as age, sex, comorbidities, type of stoma, albumin level, and leukocyte count were analyzed using Chi-Square tests. The sucralfate group demonstrated significantly greater pain reduction (ΔVAS = 0.88 ± 0.881; p = 0.003) and a higher rate of irritation improvement (84% vs 56%; p = 0.031; COR = 4.125; 95% CI: 1.092–15.585). In conclusion, off-label sucralfate provides better clinical outcomes in treating ICD, so it can be considered as an alternative therapy for patients.

***Keywords**: Sucralfate Suspension, Off-Label Therapy, Irritant Contact Dermatitis, Stoma*

Abstrak

Evaluasi Penggunaan Obat Sukralfat Suspensi secara Off Label untuk Pengobatan Dermatitis Kontak Iritan Pada Pasien Dengan Stoma. Dermatitis Kontak Iritan (DKI) merupakan komplikasi umum yang sering dialami oleh pasien stoma. Sukralfat diketahui mampu membentuk lapisan pelindung pada kulit yang teriritasi dan menstimulasi produksi faktor pertumbuhan seperti *Fibroblast Growth Factor* (FGF) dan *Epidermal Growth Factor* (EGF), sehingga mempercepat regenerasi jaringan. Di Indonesia, sediaan sukralfat suspensi sering digunakan secara *off-label* sebagai agen topikal dalam penanganan DKI. Penelitian ini bertujuan untuk mengevaluasi efektivitas sukralfat topikal + NaCl 0.9% dibandingkan dengan NaCl 0,9% terhadap perbaikan klinis pada pasien stoma dengan DKI. Penelitian retrospektif ini menggunakan data rekam medis pasien di RSPAU dr. Suhardi Hardjolukito, Yogyakarta periode Maret 2023 – Maret 2025. Dari 66 pasien stoma yang diidentifikasi, sebanyak 50 pasien memenuhi kriteria inklusi (25 mendapat sukralfat + NaCl 0.9% dan 25 mendapat NaCl 0,9%). Parameter klinis yang dinilai meliputi status perbaikan iritasi kulit dan penurunan nyeri (ΔVAS) dari hari ke-1 hingga hari ke-3. Variabel lainnya seperti usia, jenis kelamin, komorbiditas, jenis pembuatan stoma, kadar albumin, dan jumlah leukosit dianalisis menggunakan uji *Chi-Square*. Hasil menunjukkan bahwa kelompok sukralfat mengalami penurunan nyeri yang lebih besar (ΔVAS = 0,88 ± 0,881; p = 0,003) dan tingkat perbaikan iritasi yang lebih tinggi (84% vs 56%; p = 0,031; COR = 4,125; CI 95%: 1,092–15,585). Kesimpulannya, penggunaan sukralfat *off-label* memberikan hasil klinis yang lebih baik sehingga dapat dipertimbangkan sebagai terapi alternatif pada pasien dengan DKI di area stoma.

***Kata kunci**: Sukralfat Suspensi, Terapi Off-Label, Dermatitis Kontak Iritan, Stoma.*

Introduction

A stoma is a surgically created opening that allows a portion of the intestine to pass through the abdominal wall.[1] It serves as an outlet for feces and/or urine.[2] Following stoma surgery, patients may experience several complications, including irritant contact dermatitis (ICD), odor, leakage, and soiling.[3] Irritant Contact Dermatitis (ICD) is a non-immunologic inflammation of the skin characterized by erythema, mild edema, and fissuring due to exposure to external substances that trigger an inflammatory response.[4] In stoma patients, ICD is typically caused by direct contact of the skin with stoma effluent, leading to irritation and pain around the stoma site. A previous study reported that 9 out of 18 stoma patients experienced skin irritation and pain as a result of effluent exposure.[5] These symptoms can significantly affect patients' quality of life, emphasizing the need for appropriate management to relieve peristomal skin irritation and pain.[3]

Management of irritant contact dermatitis commonly includes stoma care with standard therapy using NaCl 0.9% and topical medications such as topical sucralfate or topical corticosteroids to alleviate irritation and pain. Sucralfate has been used as an alternative therapy for ICD because it has shown clinical benefits in improving skin lesions, reducing itching, and relieving pain.[6] Moreover, sucralfate possesses several potential topical properties, including analgesic, antipruritic, anti-inflammatory, wound-healing, and antibacterial effects.[7-10] In Indonesia, sucralfate is available only in two dosage forms: tablets and suspension. Some physicians have used sucralfate suspension topically (an off-label route of administration) with the expectation of achieving the same therapeutic benefits as topical formulations such as ointments or creams. However, the use of sucralfate suspension for the treatment of irritant contact dermatitis has not yet been officially approved by the BPOM or FDA. Therefore, the use of sucralfate for this indication remains off-label and requires further investigation through drug utilization evaluation studies.

RSPAU dr. Suhardi Hardjolukito is one of the hospitals in Indonesia that has utilized topical sucralfate suspension for the off-label treatment of irritant contact dermatitis in stoma patients. To date, no study has evaluated the use of topical sucralfate suspension for this purpose. Therefore, this study aimed to evaluate the off-label topical use of sucralfate suspension as a therapeutic option for irritant contact dermatitis by comparing clinical outcomes between stoma patients who received sucralfate + NaCl 0.9% and those who received NaCl 0.9% only therapy. A stoma is a surgically created opening that allows a portion of the intestine to pass through the abdominal wall.[1] Complications may occur during surgery, such as parastomal hernia, stenosis, prolapse, and stoma retraction, while postoperative complications commonly include skin irritation, pain, odor, leakage, and soiling.[3] Sucralfate has been reported to promote improvement in skin conditions, including the resolution of lesions on previously irritated areas and the reduction of itching and pain—symptoms commonly associated with irritant contact dermatitis.[5] In Indonesia, sucralfate is available only in two dosage forms: tablets and suspension. Some physicians have utilized sucralfate suspension topically (an off-label route of administration) in the expectation of achieving similar therapeutic effects to topical formulations such as ointments or creams. To date, the use of sucralfate suspension for the treatment of irritant contact dermatitis has not been officially approved by BPOM or FDA. Therefore, its application in this indication remains off-label and requires further evaluation through drug utilization studies. RSPAU dr. Suhardi Hardjolukito is among the hospitals in Indonesia that have employed topical sucralfate suspension for the management of irritant contact dermatitis in stoma patients. However, no formal evaluation of this off-label use has been conducted to date. Consequently, this study aims to evaluate the topical (off-label) use of sucralfate suspension, particularly as a therapeutic option for managing skin irritation and pain associated with irritant contact dermatitis in stoma patients.

Methods

This study utilized a retrospective cohort design based on medical record data of inpatients with stoma at RSPAU dr. Suhardi Hardjolukito, Yogyakarta, from March 2023 to March 2025. Ethical approval was

obtained from the Ethics Committee of the Faculty of Medicine, Public Health, and Nursing, Universitas Gadjah Mada (Ref. No: KE/FK/1032/EC/2025). Eligible subjects were patients with complete medical records who received either NaCl 0.9% only or sucralfate suspension + NaCl 0.9% applied topically around the stoma area three to four times daily after cleansing, for the management of irritant contact dermatitis. Exclusion criteria included patients with diabetes mellitus, purulent irritation, in-hospital mortality, or those receiving concomitant topical corticosteroid therapy alongside sucralfate. Demographic and clinical variables such as age, sex, stoma origin, comorbidities, concurrent medications, serum albumin levels, and leukocyte counts were collected for multivariate analysis. Clinical outcomes were assessed based on two parameters: (1) change in pain score (ΔVAS) from day 1 to day 3, and (2) improvement in skin irritation on day 3. Pain outcomes were analyzed using the Mann–Whitney test, while the association between treatment type (sucralfate suspension + NaCl 0.9% vs NaCl 0.9%) and irritation improvement (improved vs not improved) was examined using the Chi-square test.

Results and Discussion

In this study, medical record data of stoma patients treated at RSPAU dr. Suhardi Hardjolukito, Yogyakarta, between March 2023 and March 2025 were reviewed. A total of 66 patients were identified, of whom 16 met the exclusion criteria (7 patients died during hospitalization, 2 were referred to other hospitals, and 7 had incomplete medical records). Consequently, 50 patients met the inclusion criteria, comprising 25 who received topical sucralfate therapy + NaCl 0.9% and 25 who received NaCl 0.9% only.

Analysis of patient demographic characteristics presented in Table 1 showed that the distribution of sex between the sucralfate + NaCl 0.9% group and the NaCl 0.9% group was similar (50% male and 50% female) with a p-value of 1.000, indicating no statistically significant difference. Other patient characteristics, including the presence of comorbidities ($p = 0.136$), stoma history ($p = 0.236$), serum albumin level ($p = 0.107$), and leukocyte count ($p = 1.000$), also showed no significant differences between the two groups. However, a significant difference was observed in the age variable. Patients aged >65 years were more prevalent in the NaCl group (73.3%) than in the sucralfate + NaCl 0.9% group (26.7%) ($p = 0.031$). Increasing age is known to reduce skin elasticity, slow epithelial cell regeneration, and impair immune response, which may delay wound healing and influence clinical outcomes related to skin irritation.[1,11]

Patients in this study not only received sucralfate and/or NaCl 0.9% therapy but also received various additional treatments according to their individual clinical indications. Antibiotics and analgesics were administered to all patients, which is understandable since most were postoperative cases requiring antibiotics for prophylaxis or infection management and analgesics for postoperative pain control. In addition, 15 patients (21.8%) received other medications such as peptic ulcer prophylaxis, antihypertensive agents, antipyretics, antiemetics, and other supportive therapies depending on their clinical condition. Albumin supplementation was administered to only four patients, indicating that hypoalbuminemia occurred in a small subset of patients, yet it still required correction due to its potential to impair wound healing. This pattern of adjunctive therapy reflects the general characteristics of hospitalized postoperative patients or those with comorbidities who require comprehensive management to support the healing process.

In addition to therapy during hospitalization, most patients also receive sucralfate as follow-up therapy (home therapy) to ensure that the peristomal skin healing process continues at home. The purpose of this home therapy is to maintain the protective layer that has formed during treatment, prevent recurrence of irritation, and accelerate tissue regeneration. Therefore, educating patients and their families is very important. Education includes how to use sucralfate topically, frequency of administration, stoma area hygiene, and signs of irritation or infection that should be watched out for, which must be provided to patients or their families (caregivers). Good education can increase patient compliance, reduce the risk of recurrence, and support optimal clinical improvement. Clinical outcomes in stoma patients with irritant contact dermatitis were assessed through two parameters: pain intensity using the Visual Analogue Scale (VAS) and the evaluation of skin irritation improvement status. The average Length of Hospital Stay (LOS) among patients

was 5.6 days, with a minimum stay of 3 days. Therefore, VAS and irritation assessments were conducted on day 1 and day 3 to evaluate early-phase clinical changes during the healing process. This approach aligns with the findings of Tambunan (2008), who performed daily serial observations and reported the most evident clinical improvement on the third day of treatment. The inflammatory phase is known to be most active within the first 72 hours postoperatively, making day 3 a critical time point for evaluating clinical outcomes in stoma patients with irritant contact dermatitis.[12]

Table 1. Patient Demographic Data

Patient Characteristics	Sucralfate + NaCl 0,9% n (%)	NaCl 0,9% n (%)	p-value
Gender			
Female	10 (50)	10 (50)	1.000
Male	15 (50)	15 (50)	
Age			
< 65 years	21 (60)	14 (40)	0.031*
> 65 years	4 (26.7)	11 (73.3)	
Comorbidities			
Present	19 (57.6)	14 (42.4)	0.136
None	6 (35.3)	11 (64.7)	
Stoma history			
Post op colostomy	9 (37.5)	15 (62.5)	0.236
Post op ileostomy	3 (60)	2 (40)	
Previous stoma placement	13 (61.9)	8 (38.1)	
Serum Albumin Level			
Normal	9 (69.2)	4 (30.8)	0.107
Hypoalbuminemia	16 (43.2)	21 (56.8)	
Leukocyte counts			
Normal	10 (50)	10 (50)	1.000
Leukocytosis	15 (50)	15 (50)	

Note : chi aquare tests, * $p < 0.05$ was considered statistically significant

Table 2. Other drug therapies (besides sucralfate + NaCl 0.9% and NaCl 0.9%)

Therapy	Frequency (n = 69)	Percentage (%)
Albumin	4	5,8
Analgesic	25	36,2
Antibiotic	25	36,2
Other therapy	15	21,8

In this study, topical sucralfate therapy was administered by applying sucralfate suspension directly to the affected peristomal skin area with irritant contact dermatitis. The application frequency was 3–4 times daily after cleansing and drying the stoma area with NaCl 0.9%. Meanwhile, NaCl 0.9% served as the standard therapy in the form of an irrigation solution used to clean the peristomal skin. The cleansing procedure was performed by gently wiping the stoma area with sterile cotton or gauze soaked in NaCl 0.9%, followed by gentle drying. The use of NaCl 0.9% aimed to remove residual exudate and debris, maintain physiological skin moisture, and reduce the risk of bacterial colonization that could exacerbate irritation.

Based on Table 3, both treatment groups showed a reduction in pain scores (ΔVAS). The mean VAS score in the sucralfate + NaCl 0.9% group decreased from 2.24 ± 0.926 on day 1 to 1.36 ± 0.490 on day 3, with a mean reduction (ΔVAS) of 0.88 ± 0.881. In contrast, the mean VAS score in the NaCl group decreased only slightly, from 1.76 ± 0.779 on day 1 to 1.72 ± 0.792 on day 3, with a much smaller mean reduction (ΔVAS) of

0.04 ± 1.060. Statistical analysis using the Mann–Whitney test revealed a significant difference in ΔVAS between the two groups (p = 0.003), indicating that sucralfate therapy provided a significantly greater reduction in pain compared to NaCl 0.9%. Although the differences in absolute VAS scores between groups on day 1 (p = 0.068) and day 3 (p = 0.054) were not statistically significant, the larger reduction trend observed in the sucralfate group suggests a more pronounced therapeutic effect in alleviating pain among patients with peristomal irritant contact dermatitis. This finding is consistent with the study conducted by Tambunan (2008), which also reported a significant reduction in VAS scores ($p < 0.05$) beginning on the third day of observation. The analgesic mechanism of sucralfate is attributed to its cytoprotective properties, including the formation of a protective barrier over mucosal surfaces and the stimulation of prostaglandin and Epidermal Growth Factor (EGF) secretion, which accelerate tissue regeneration and angiogenesis.[10]

Table 3. Average VAS Score Among Patients

Day	1	3	Δ VAS
Sucralfate + NaCl 0.9%	2.24 ± 0.926	1.36 ± 0.490	0.88 ± 0.881
NaCl 0.9%	1.76 ± 0.779	1.72 ± 0.792	0.04 ± 1.060
p-value	0.068	0.054	0.003*[a]

Note: ΔVAS = difference in Visual Analog Scale; a = Mann–Whitney test; *p < 0.05 was considered statistically significant.

Table 4. Clinical Outcome of Irritation Improvement

Therapy	Improvement of irritation		COR (CI 95%)	*p-value*
	Improved	Not improved		
	n (%)	n (%)		
Sucralfate + NaCl 0.9%	21 (84)	4 (16)	4,125 (1.092- 15.585)	0.031*
NaCl 0.9%	14 (56)	11 (44)		
Total	35 (70)	15 (30)		

Note: chi-square test; COR = Crude Odds Ratio; CI = Confidence Interval; *p < 0.05 is considered statistically significant

The proportion of patients who experienced improvement in peristomal skin irritation was higher in the sucralfate + NaCl 0.9% group compared with the NaCl 0.9% group (Table 4). In the sucralfate group, 21 patients (84%) showed improvement, while only 4 patients (16%) did not. In contrast, in the NaCl group, 14 patients (56%) experienced improvement and 11 patients (44%) showed no improvement. Statistical analysis using the Chi-square test yielded a p-value of 0.031 ($p < 0.05$), indicating a significant difference between the two groups. The crude odds ratio (COR) of 4.125 (95% CI: 1.092–15.585) suggests that patients receiving sucralfate therapy were approximately 4.1 times more likely to experience improvement in skin irritation than those receiving NaCl 0.9%. Sucralfate exerts its therapeutic effect by forming a protective layer over the affected area through the interaction between negatively charged polyanions in sucralfate and positively charged wound proteins such as albumin and fibrinogen. This interaction creates a physical barrier that prevents further tissue damage and infection.[13] The protective film formed on the irritated mucosa acts as a shield against fecal and microbial irritation, thereby reducing itching and discomfort.[7] Additionally, sucralfate enhances the bioavailability of growth factors, stimulates angiogenesis, accelerates cell proliferation, and reduces cellular apoptosis—all of which contribute to faster tissue regeneration.[14]

In the study conducted by Yaşar et al. (2018), sucralfate therapy demonstrated favorable epithelialization outcomes.[15] Similarly, Amaturo et al. (2020) reported that sucralfate produced significant clinical improvement in pruritus symptoms, while Tambunan (2008) also found that sucralfate reduced erythema in patients with irritant contact dermatitis associated with stoma ($p < 0.05$).[7, 12] In the present study, no patients experienced serious adverse effects related to topical sucralfate use, such as peristomal skin

infection or hypersensitivity reactions. This finding supports the good safety profile of sucralfate when used as a topical therapy for stoma patients with irritant contact dermatitis. However, one patient did not show clinical improvement after topical sucralfate administration during the observation period. In this case, therapy was switched to mometasone furoate, a topical corticosteroid that suppresses local inflammatory responses and reduces irritation. This therapeutic adjustment aligns with clinical practice recommendations suggesting the use of moderate- to high-potency topical corticosteroids in cases of peristomal dermatitis unresponsive to initial therapy, to prevent lesion progression and promote faster recovery.

Table 5. The Relationship Between Patient Characteristics and Clinical Outcome Improvement

Patient Characteristics	Improvement of irritation		*p-value*
	Improved	Not improved	
	n (%)	n (%)	
Gender			
Female	19 (63,3)	11 (36.7)	0.208#
Male	16 (80)	4 (20)	
Age			
< 65 years	26 (74.3)	9 (25.7)	0.312
> 65 years	9 (60)	6 (40)	
Comorbidities			
Present	25 (75.8)	8 (24.2)	0.216#
None	10 (58.8)	7 (41.2)	
Stoma history			
Post op colostomy	16 (66.7)	8 (33.3)	
Post op ileostomy	3 (60)	2 (40)	0.688
Previous stoma placement	16 (76.2)	5 (23.8)	
Serum Albumin Level			
Normal	9 (69.2)	4 (30.8)	0.944
Hypoalbuminemia	26 (70.3)	11 (29.7)	
Leukocyte counts			
Normal	13 (65)	7 (35)	0.529
Leukocytosis	22 (73.3)	8 (26.7)	

Note: chi-square test; *p < 0.05 is considered statistically significant; #p < 0.25 is continued for multivariate testing

Based on Table 5, no significant association was found between patient characteristics and improvement in peristomal skin irritation (p > 0.05). For the sex variable, the proportion of improvement was slightly higher among female patients (63.3%) compared with males (60%), although this difference was not statistically significant (p = 0.208). Age also showed no significant influence, despite patients aged <65 years exhibiting a higher proportion of improvement (74.3%) compared with those aged >65 years (60%) (p = 0.312). Similarly, the presence of comorbidities, type of stoma (colostomy or ileostomy), and history of previous stoma formation were not significantly associated with clinical improvement in irritation (p > 0.05). Nutritional status, as assessed by serum albumin levels, also showed no significant difference, with irritation improvement observed in 69.2% of patients with normal albumin levels and 70.3% of patients with hypoalbuminemia (p = 0.944). Leukocyte count did not influence clinical outcomes either, with irritation improvement seen in 73.3% of patients with leukocytosis and 61.9% of those with normal leukocyte levels (p = 0.529).

The study by Sheinenzon et al. (2021) demonstrated a significant negative correlation between serum albumin and C-reactive protein (CRP) (r = −0.311) as well as leukocyte count (r = −0.157), indicating that albumin levels decrease as inflammation increases.[16] Hypoalbuminemia prolongs the inflammatory phase, impairs collagen synthesis, and slows epithelialization, thereby delaying the resolution of skin irritation. This

condition also enhances nociceptor sensitivity and exacerbates pain, further worsened by tissue edema resulting from decreased plasma oncotic pressure.[16] During the initial inflammatory phase, leukocytes migrate to the wound site through chemotactic mechanisms regulated by chemokines and adhesion molecules. This migration triggers the release of proinflammatory mediators such as cytokines, prostaglandins, bradykinin, and nerve growth factors, which activate nociceptors (Aδ and C fibers), leading to pain sensation.[17] Elevated leukocyte counts reflect greater inflammatory activity, which is commonly associated with increased pain severity. However, in the present study, demographic factors (age and sex) and clinical factors (comorbidities, stoma history, albumin, and leukocyte levels) were not significantly associated with the improvement of peristomal skin irritation.

Although no statistically significant associations were observed between patient characteristics and irritation improvement, several variables with p-values < 0.25 met the criteria for inclusion in multivariate analysis. These variables included sex (p = 0.208) and comorbidities (p = 0.216). According to epidemiological analysis principles, variables with potential associations (p < 0.25) in bivariate analysis should be included in the multivariate model to control for possible confounding effects, even if they are not statistically significant in univariate analysis. This approach allows for a more accurate assessment of the independent influence of each factor on the improvement of peristomal skin irritation following treatment with sucralfate or NaCl 0.9%.

Tabel 6. Multivariate analysis of clinical outcomes of irritation

Variabel	AOR (CI 95%)	*p-value*
Therapy received (NaCl vs Sucralfate)	3,969 (0,998 – 15,789)	0,050
Gender (Female vs Male)	0,378 (0,092 – 1,559)	0,178
Comorbidities (None vs Present)	1,849 (0,480 – 7,115)	0,372

Note: logistic regression test; AOR = Adjusted Odds Ratio; CI = Confidence Interval; *p < 0.05 is considered statistically significant.

Multivariate analysis using logistic regression (Table 6) showed that the treatment variable (NaCl 0.9% vs sucralfate + NaCl 0.9%) demonstrated a near-significant association with improvement in peristomal skin irritation, with an adjusted odds ratio (AOR) of 3.969 (95% CI: 0.998–15.789; p = 0.050). This finding indicates that patients receiving sucralfate therapy were almost four times more likely to experience irritation improvement compared with those treated with NaCl 0.9%, after controlling for sex and comorbidities. The variables of sex (AOR = 0.378; 95% CI: 0.092–1.559; p = 0.178) and comorbidities (AOR = 1.849; 95% CI: 0.480–7.115; p = 0.372) did not show significant effects on irritation improvement outcomes. These results further support the bivariate analysis, suggesting that sucralfate therapy has a potentially greater therapeutic effect, while demographic and clinical variables did not significantly influence clinical outcomes after adjusting for confounding factors. In addition to these factors, several other variables may warrant further investigation. The type and quality of stoma appliances used are known to influence the development of irritant contact dermatitis. Poorly fitting pouches, those with adhesive strength that is either too strong or too weak, or those prone to leakage can lead to continuous exposure of the peristomal skin to irritant exudates or intestinal effluent. Such exposure increases the risk of skin barrier damage, triggers inflammatory responses, and results in symptoms such as erythema, itching, and pain.

Conclusions

The group of patients who received off-label sucralfate therapy showed a significantly greater reduction in pain (ΔVAS) and a higher proportion of peristomal skin irritation improvement. Patients treated with off-label sucralfate were 4.1 times more likely to experience irritation improvement compared with those

receiving NaCl 0.9% only therapy. Patient-related factors (age, sex) and clinical factors (comorbidities, stoma history, serum albumin levels, and leukocyte counts) were not significantly associated with clinical outcomes of irritation improvement.

Conflict of Interest

The authors declare no financial conflict of interest. However, the researchers are affiliated with RSPAU dr. Suhardi Hardjolukito, where the study was conducted. The research was carried out independently, and the institutional affiliation did not influence the study design, data collection, analysis, or interpretation of the results.

Acknowledgment

The authors received no specific grant or financial support for this research.

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