

Analgesic efficacy of an ibuprofen-releasing foam dressing compared with local best practice for painful exuding wounds

- **Objective:** To examine if wound aetiology has an effect on the pain-relieving properties of an ibuprofen-releasing foam dressing, which was previously shown to reduce pain in wounds of various aetiologies, compared with local best practice (LBP).
- **Method:** This was a secondary analysis of data from a multicentre, randomised, parallel group trial of patients with painful exuding wounds of various aetiologies. Wound aetiology was determined at enrolment. Of 853 patients enrolled into the trial, 688 belonged to a wound aetiology subgroup that included > 25 patients and were included in the analysis reported here. Patients were randomised to a dressing containing 112.5mg of ibuprofen (ibuprofen foam) or to LBP for 5 days. Patients recorded pain relief and pain intensity daily. The main endpoint was the proportion of patients who, from day 1 to day 5, reported a summed pain relief score > 50% of the total maximum pain relief score (TOTPAR_{DS>50%}) and the corresponding number needed to treat (NNT) for each wound aetiology subgroup. Further analyses included the proportion of patients who, on a daily basis, reported pain relief > 50% of the maximum daily pain relief, the proportion of patients who, on day 5, experienced a reduction in pain intensity of > 50% of the maximum score (PID_{DS>50%}), and if PID_{DS>50%} was related to baseline pain intensity.
- **Results:** Patients were categorised by the following five wound types: arterial, venous, and mixed arterial-venous leg ulcers, vasculitis and traumatic ulcers. The ibuprofen foam dressing was associated with significantly greater pain relief than LBP in all different wound aetiology subgroups, whether chronic or traumatic (acute). Overall, TOTPAR_{DS>50%} was 55% in the ibuprofen foam group and 24% in the LBP group ($p < 0.0001$; NNT, 3.2). The pain intensity evaluations revealed similar results in favour of ibuprofen foam compared with LBP. No correlation was observed between PID_{DS>50%} and initial pain intensity.
- **Conclusion:** In this study, the ibuprofen foam dressing was shown to consistently relieve wound pain in exuding wounds of various aetiologies, irrespective of basal pain intensity. The data suggest that local pain relief by an ibuprofen foam dressing is possible in the most common, painful, exuding, chronic and acute/traumatic wounds and so is a safer alternative to systemic pain treatment.
- **Conflict of interest:** Of the ten authors involved in the preparation of this manuscript, seven declare that they have no conflicts of interest. One is a member of the Wound Advisory Forum for Coloplast A/S, Denmark. Two are employees of Coloplast A/S, Denmark.

analgesia; wound pain; ibuprofen; wound dressing

Pain is a common symptom for patients with chronic, exuding, cutaneous wounds¹⁻³ and can significantly interfere with a person's quality of life and general function. Prevalence studies have shown that pain is associated with both venous and mixed aetiology leg ulcers in a high proportion of cases, and that approximately half of these patients use oral analgesics.^{2,4}

In 2008, a randomised, double-blind, controlled clinical trial involving 122 patients with venous leg ulcers observed that a non-adhesive foam dressing, which continuously released low dose ibuprofen into the wound, achieved significantly greater

wound pain relief than the comparator, a similar foam without ibuprofen, with no difference in wound area reduction and without compromising other safety parameters.⁵

In a separate, real-life RCT, which comprised a large, randomised study of 853 patients with painful, chronic exuding wounds of various aetiologies, comparing the ibuprofen foam (Biatain Ibu) with local best practice (LBP), the experimental group experienced statistically significant relief from temporary and persistent pain and a reduction in pain intensity, when compared with LBP.⁶ The aim was to compare Biatain Ibu with the most commonly used treatment practice, as opposed to the control used

V. Arapoglou,¹ MD PhD;
K. Katsenis,¹ MD PhD;
K.N. Syrigos,² MD PhD;
E.P. Dimakakos,² MD PhD;
N. Zakopoulou,³ MD;
D. Tsoutsos,⁴ MD PhD;
K. Gjødsbøl,⁵ PhD;
C. Glynn,⁶ MD;
E. Schäfer,⁷ MD PhD;
B. Petersen,⁵ MD.
¹ University of Athens
Areteiaon Hospital,
Greece;

continued on page 320

2 Oncology Unit of 3rd Department of Medicine, School of Medicine, University of Athens, Sotiria General Hospital, Athens, Greece;
 3 Department and Leg Ulcer Unit, 'A. Syggros' Hospital, Athens, Greece;
 4 Department of Plastic Surgery, Microsurgery and Burn Center, General Hospital of Athens 'G. Gennimatas', Greece;
 5 Medical Affairs, Coloplast A/S, Denmark;
 6 BMI Oxford Clinic, Headington, Oxford, UK;
 7 Wound Centre, Hamburg, Germany.
 Email: DKBIR@coloplast.com

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- In the more traditional, double-blind RCT described above.⁵ As LBP reflects the standard treatment used in the participating clinics at the time of the study, it was considered to represent the most relevant benchmark against which to compare the ibuprofen foam dressing to provide results that are useful for everyday clinical practice.
- Since the effect of the ibuprofen foam was first investigated on leg ulcers of venous origin only,^{5,7} with venous leg ulcers also comprising the largest aetiology group in the subsequent real-life RCT,⁶ a secondary analysis was undertaken to re-examine the data in the Domenech et al. trial with respect to pain relief outcome and wound aetiology, variables not considered in the original evaluation. In addition, the raw data were re-analysed using improved, more robust measures for analgesic efficacy than those used at the time of the original analysis.^{8–13}
- Method**
- Study design and patients**
- The study design and methodology have been described in detail previously.⁶ Briefly, this was a multicentre (184 centres), comparative, randomised, parallel group trial, conducted in 12 countries between May 2006 and August 2007. The study included both inpatients and outpatients with painful, exuding wounds of various aetiologies, randomised to treatment with either ibuprofen foam or LBP.
- The main inclusion and exclusion criteria were:
 - Over 18 years of age
 - Non-infected, painful wound > 1cm² (the dressing must be larger by at least 2cm in any direction)
 - Moderate to severe levels of exudate
 - No known hypersensitivity to NSAIDs or acetylsalicylic acid.
- The treatment period was 7 ± 2 days. Concomitant medications were allowed, but patients were asked not to change the dosing of any pain-relieving medications during the study period.
- At enrolment, the investigators classified wounds according to their aetiology. The following seven wound aetiology subgroups were identified: arterial leg ulcers; venous leg ulcers; mixed arterial and venous leg ulcers; wounds due to vasculitis; postoperative wounds; traumatic wounds; and donor site wounds. The latter three groups essentially comprised 'traumatic or acute' wounds and were, therefore, combined and compared with the other four groups of patients with different types of chronic wounds/pain.
- Only patients in wound aetiology subgroups containing more than 25 patients (i.e. subgroups with more than 25 wounds) were included in the current analysis. Therefore, of the 853 patients investigated in the original trial, 688 were evaluable. The remaining 165 patients had wounds with a variety of different aetiologies.
- The randomised trial was conducted according to local regulations, the Declaration of Helsinki II,¹⁴ the EC Medical Device Directive,¹⁵ and the international ISO standard on clinical investigation of medical devices for human subjects.¹⁶ Ethics committee approval was granted and written informed consent was obtained from all patients.
- Interventions**
- The test dressing (Biatain Ibu, Coloplast A/S, Humlebaek, Denmark) is designed to provide a moist wound healing environment and manage exudate. It contains 0.5mg/cm² ibuprofen homogeneously dispersed throughout the foam.¹⁷ In the presence of exudate, ibuprofen is released continuously into the wound bed. The amount of ibuprofen released depends upon the degree of exudate. The more exudate, the more ibuprofen is released into the wound bed.
- One dressing (15x15cm) contains 112.5mg of ibuprofen. The comparator treatment was LBP: the best standard dressing used at the investigator site, at the time of the study, for painful exuding wounds.
- Outcome measures**
- As previously described,⁶ patients assessed their pain twice daily, keeping a record in a diary. Pain relief was evaluated using a five-point scale (no relief=0, slight=1, moderate=2, marked=3, complete pain relief=4) and pain intensity was assessed using an 11-point numerical box rating scale (0=no pain and 10=worst possible pain).¹⁸
- The main endpoint of the analysis was the proportion of patients who, from day 1 to day 5 reported a summed pain relief score >50% of the total maximum pain relief score (TOTPAR_{DS>50%}).
- From this, the number needed to treat (NNT) for ibuprofen foam vs LBP was derived. The NNT is a measure calculated on the inverse of the absolute risk reduction. It represents the average number of patients who need to be treated for one patient to benefit from the treatment and has the advantage that it conveys both statistical and clinical significance to the clinician.¹⁹
- A pain relief score of >50% of the total maximum pain relief score is a validated parameter of analgesic efficacy and a clinically meaningful outcome measure of relevant pain relief.^{8,9,13} Only data from the patients' evening assessments were used in this analysis to evaluate pain during daytime.
- The following parameters were also evaluated: the proportion of patients who, on a daily basis, reported >50% of maximum daily pain relief, the proportion of patients who, on day 5, experienced a reduction in pain intensity of >50% (PID_{DS>50%}) of the pain intensity at the baseline (day 0), and the corresponding NNTs. PID_{DS>50%} was also correlated with baseline pain intensity to determine if the initial pain intensity levels affect pain relief.

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continued on page 325

Table 1. Patient demographics at baseline in the ibuprofen foam and LBP groups.

Wound aetiology	Ibuprofen foam			LBP		
	No. of pts (male/female)	Median age (years)	Median wound duration (years)	No. of pts (male/female)	Median age (years)	Median wound duration (years)
Venous leg ulcer	189 (69/120)	70	0.5	159 (54/105)	70	0.5
Arterial leg ulcer	40 (16/24)	75	0.4	38 (28/10)	76	0.7
Mixed aetiology	74 (32/42)	76	0.7	44 (23/21)	75	1.0
Vasculitis	23 (6/17)	72	0.4	16 (3/13)	76	0.7
Traumatic	60 (28/32)	60	0.1	45 (20/25)	66	0.2
Total	386 (151/235)	70	0.5	302 (128/174)	72	0.6

Pts = patients

Statistics

As all patients were evaluated for at least 5 days (7 ± 2 days), a day 5 cutoff was selected to ensure the largest number of observations. All statistical analyses were performed at the 5% significance level. Differences between sizes of effect were analysed using the Chi-squared test, while regression analysis was used to evaluate the correlation between initial pain intensity and the proportion of patients who, on day 5, experienced a reduction in pain intensity of >50%.

Results

Patients and wound aetiology

Five groups of patients with different wound aetiologies were established (Table 1). Venous, arterial, and mixed leg ulcer aetiologies comprised 48% ($n=330$), 11% ($n=76$) and 17% ($n=117$) of the 688 patients included in this analysis, respectively. No clinically meaningful differences were observed between the baseline demographic data for patients in the ibuprofen foam intervention group and the LBP control group. The most common LBP treatment was moist wound healing dressings (including foams, dressings with active components, hydrogels, Hydrofiber, alginates and hydrocolloids), which were used for 80% ($n=550$) of patients; gauze was used in 7% ($n=48$) and other remedies, not specified in the RCT, in 13% ($n=89$).

Efficacy outcomes

Results for the main endpoint ($\text{TOTPAR}_{\text{D5}>50\%}$) are shown for both the study population overall and also by wound aetiology subgroup in Table 2. For the overall study population, the percentage who, on day 5, reported a summed pain relief score of >50% of the total maximum pain relief score ($\text{TOTPAR}_{\text{D5}>50\%}$) was significantly higher in the ibuprofen foam group than in the LBP group (55% and 24%, respectively; $p<0.0001$). The difference

between the two treatment groups ranged from 19% for venous leg ulcers to 41% for arterial leg ulcers. The corresponding NNTs ranged from 2.4 to 5.2, with an NNT of 3.2 for all aetiologies combined. The proportion of patients who, on a daily basis, reported pain relief >50% of the maximum score is shown by wound aetiology subgroup in Fig 1. The plot of the curves for the ibuprofen foam and LBP groups appear to follow two different courses. After the first day of treatment (day 1), 20–32% of patients in the ibuprofen foam group reported >50% pain relief, compared with 4–10% of patients in the LBP group. Over the following days, the proportion of patients with >50% pain relief appeared to increase overall in the ibuprofen foam group but not in the LBP group.

The proportion of patients who, on day 5, experienced a reduction in pain intensity of >50% compared to baseline ($\text{PID}_{\text{D5}>50\%}$) is shown in Table 3, for both the study population overall and by wound aetiology subgroup. $\text{PID}_{\text{D5}>50\%}$ ranged from 40% to 59% in the ibuprofen foam group and from 7% to 36% in the LBP group. The results significantly favoured the ibuprofen foam treatment in all wound aetiology subgroups, except traumatic, which did not reach statistical significance compared with LBP. The corresponding NNTs ranged from 3.1 to 6.2.

The mean pain intensity levels at the baseline ranged from 4.3 to 7.1 across the different wound aetiology subgroups, with no statistically significant difference detected between the ibuprofen foam intervention group and LBP group. No correlation was observed between $\text{PID}_{\text{D5}>50\%}$ and initial pain intensity, indicating that the proportion of patients who experienced a clinically relevant reduction in pain intensity on day 5 compared with baseline pain intensity, was independent of the baseline pain intensity (Fig 2).

Discussion

Analysis of the data from this large, randomised, multicentre trial demonstrated that ibuprofen foam provided clinically meaningful pain relief in significantly more patients than current LBP. This effect was consistent for the various different, common types of chronic and traumatic, painful, exuding cutaneous wounds.

LBP was chosen as the active comparator,⁶ comprising moist wound healing treatments, such as foams, dressings with active components, hydrogels, Hydrofiber, alginates and hydrocolloids, in 80% of patients, while the remaining 20% of patients were treated with gauze or other unspecified dressings. As LBP reflects the treatment administered in current, real-life daily practice, it was considered to represent the most clinically relevant benchmark against which to compare the ibuprofen foam dressing.

Data were evaluated up to 5 days, which has been shown to be sufficient to evaluate the ability of a dressing to relieve persistent wound pain.^{5,20,21} Perception of pain changes over time in patients suffering from chronic pain states.²² Therefore, the data will be more reliable if pain measurements are performed over relatively short periods of time. For this reason, pain was measured in two separate 5-day periods in a previously published RCT of longer duration.⁵ In relation to traumatic wounds, a short time period was also considered an advantage, since pain will naturally decrease as the wounds heal.

For pain relief measurements, a 50% cut-off point is considered appropriate for defining satisfactory and clinically meaningful analgesia in connection with acute pain associated with dental extraction, headache and dysmenorrhoea.^{8,9,13} The corresponding cut-off point for chronic pain, such as that from cancer, diabetic neuropathy, post-therapeutic neuralgia and osteoarthritis, is estimated to be about 30%.⁸ For pain intensity measurements, a 30–40% pain reduction is considered the minimal clinically important improvement for both acute and chronic pain.^{10–12} In the original study, the cut-off point was taken as >20% for pain relief and pain intensity outcomes (five categories: none–slight, moderate, marked and complete, with the cut-off point as slight), however, it was raised to >50% for the present study. This conservative approach helps to ensure the clinical relevance of the findings, which is particularly important given the non-blinded study design.

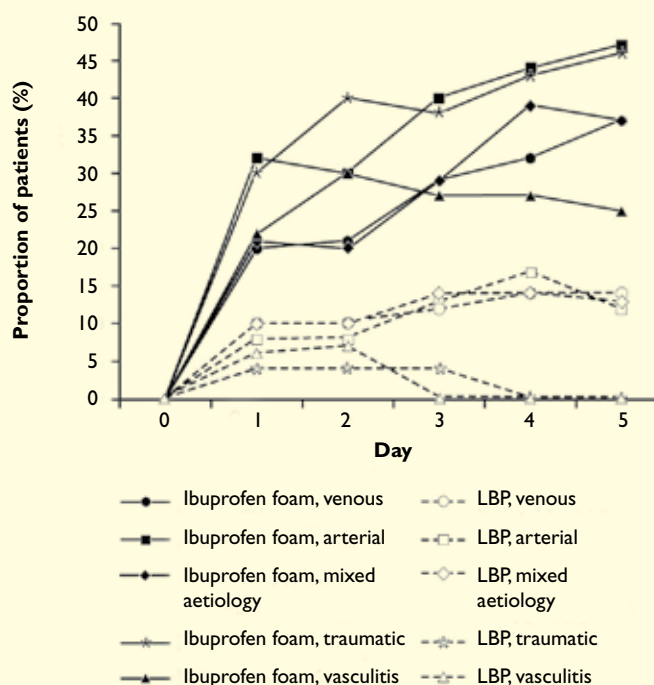
The NNT describes the number of patients who need to be treated for one patient to benefit compared with a control in a clinical trial.¹⁹ On average, 55% of patients treated with ibuprofen foam in this study reported clinically meaningful pain relief over the course of the study, compared with 24% in the

Table 2. Proportion of patients who reported a summed pain relief score >50% of the total maximum pain relief score for day 1 to 5 (TOTPAR_{DS>50%}).

Wound aetiology	Ibuprofen foam (%)	LBP (%)	p value	NNT
Venous leg ulcer	49	30	0.0003	5.2
Arterial leg ulcer	68	27	0.0003	2.4
Mixed aetiology	55	25	0.0013	3.3
Vasculitis	43	13	0.0392	3.3
Traumatic	62	23	<0.0001	2.6
Total	55	24	<0.0001	3.2

NNT = number needed to treat

Fig 1. Proportion of patients who, on a daily basis, reported a pain relief score >50% of the maximum daily pain relief score.



LBP group. This is equivalent to a NNT of 3.2. Oral analgesics for acute pain relief, such as ibuprofen 200/400mg or paracetamol 500/1000mg, have NNTs in the region of 2 to 4 compared with placebo (based on a 50% cut-off point). These are considered to offer effective pain relief, whereas analgesics with NNTs above 10 are deemed ineffective.^{23,24} For chronic pain states, NNTs for oral analgesics are in the region of 3–5.^{23,24}

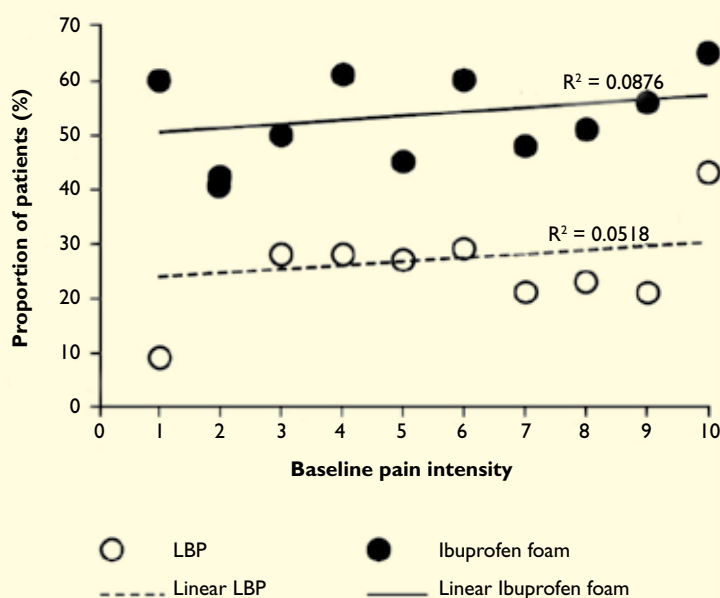
In this study, the ibuprofen foam provided pain relief in the same order of magnitude as commonly used oral analgesics, for both acute and chronic

Table 3. Proportion of patients who, on day 5, experienced a reduction in pain intensity of >50% compared with baseline (PID_{D5>50%}).

Wound aetiology	Ibuprofen foam (%)	LBP (%)	p value	NNT
Venous leg	57	30	<0.0001	3.7
Arterial leg	56	24	0.0047	3.1
Mixed aetiology	59	29	0.0017	3.3
Vasculitis	40	7	0.0207	3.3
Traumatic	52	36	0.1004	6.2
All	55	28	<0.0001	3.7

NNT = number needed to treat

Fig 2. Proportion of patients who, on day 5, experienced a reduction in pain intensity of >50% compared with baseline (PID_{D5>50%}), correlated to baseline pain intensity.



pain. Furthermore, it has previously been shown that the ibuprofen could not be detected systemically when the ibuprofen foam was used.⁷ This is of particular importance for elderly, fragile patients who are prone to suffer from systemic side effects of commonly used analgesics such as NSAIDs.

Evaluation of data on a daily basis revealed that 4–10% of patients in the LBP group reported effective pain relief after day 1 of treatment, although this proportion remained largely unchanged throughout the study. This observation is not unexpected because moist wound healing can provide some pain relief but is unlikely to increase pain relief

over the course of 5 days,¹⁸ which is too short a time frame for wound healing. In contrast, 20–32% of patients in the ibuprofen foam group reported pain relief after day 1, increasing to 37–47% of patients after day 5 in all wound aetiology subgroups, except in the vasculitis group where pain relief did not change over time. The increasing number of ibuprofen foam-treated patients who experienced clinically meaningful pain relief over time could be explained by the presence of ibuprofen in the wound bed. The results in the vasculitis subgroup could be related to the broad range of disease states that were presumably included within this category, which may have different pain mechanisms.

The variation in the number of responders between wound types, especially for TOTPAR_{D5>50%} (ranging from 43% to 68% for the ibuprofen foam), which we believe to be the most sensitive measure, resulted in quite variable NNTs (ranging from 2.4 in arterial ulcers, to 5.2 in venous leg ulcers). This is very likely due to the non-uniformity of pain quality of the different wound types. In chronic leg ulcers, for example, there is often a neuropathic component, which may explain the relatively high NNT for these wounds.

This study suggests that pain relief was effective for the acute pain experienced by patients with traumatic ulcers. Predictably, the difference between the ibuprofen foam intervention group and the LBP group on day 5 was not significant for these patients, as acute pain following trauma resolves with time, irrespective of treatment.

The study showed that clinically meaningful pain relief can be obtained independent of the baseline pain level, which ranged from 4.3–7.1. This is of considerable clinical importance, because it underlines that, irrespective of the initial pain level, the acute and chronic pain from cutaneous exuding wounds can be reduced and should be treated.

The study has a number of limitations. The results reported are based on a *post hoc* analysis of raw data from the original study.⁶ Concomitant intake of oral analgesics can be a confounder; such data were not examined in the present study but were examined in the original data.⁶ Despite being asked not to alter the dosage, more patients in the treatment group reduced analgesic intake compared with the LBP group, which makes the results appear even stronger. Other potential confounding variables, like age and ulcer duration, did not differ between groups and are unlikely to be of importance for outcomes.

As it was an open study design, there was the inherent possibility of treatment bias from patients or study personnel. Although baseline pain intensity was assessed before randomisation, and therefore not susceptible to bias, it could be argued that the higher initial improvement (day 1) in the ibuprofen

foam group compared with the LBP group could be caused by such bias. However, as the number of patients reporting pain relief increased on a daily basis in the ibuprofen foam group, any possible placebo effect is likely to be minimal. As discussed above, the cut-off point for relevant pain relief should be at least 30–40%,^{10–13} and because this study was of open design, a conservative cut-off point of pain relief >50% was also employed to reduce any possible impact of bias.

Conclusion

The ibuprofen foam dressing provides effective, clinically meaningful pain relief for exuding acute and chronic cutaneous wounds of various aetiologies irrespective of baseline level of pain. Compared with LBP, primarily comprising moist wound healing dressings, the overall NNT for ibuprofen foam was 3.2; this is in the same region as the NNTs for oral NSAIDs compared with placebo in acute and chronic pain states. ■

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Bulletin board

Wounds-at-risk (W.A.R.) scoring system

The wounds-at-risk (W.A.R.) scoring system is a new clinical classification for 'risk wounds', indicating when to use antiseptics.

By adding up a series of differently weighted risk causes, with the values 1, 2 or 3, it recommends antimicrobial treatment when the total is more than or equal to three.

Developed by an interdisciplinary team and supported by

Lohmann & Rauscher, this scoring score represents expert recommendation to simplify the term 'risk wound', based on professional discussion and current knowledge.

This helps health professionals select which situations justify the use of antiseptics to guard against wound infection, preventing the overuse of topical antimicrobials.

Though not yet verified in practice, the W.A.R. score improves risk assessment of

wounds at risk of infection, helping to develop appropriate general treatment regimes with a focus on the prevention of wound infection.

The wounds-at-risk score is published in:

Dissemond, J., Assadian, O., Gerber, V. et al. Classification of wounds at risk (W.A.R. score) and their antimicrobial treatment with polihexanide — A practice-oriented expert recommendation. *Skin Pharmacol Physiol*. 2011; 24: 5, 245–255.

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