

# 第 1 6 号

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総会局所用メトロニダゾール単剤は酒さの寛解を維持する。

抗炎症作用

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### Topical Metronidazole Maintains Remissions of Rosacea

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San Francisco — Topical metronidazole gel alone is effective at preventing relapse of rosacea in 80% of patients who have been successfully treated with oral tetracycline and topical metronidazole together, experts say. And now, thanks to new data, physicians can better predict which patients will most likely be maintained in remission on topical metronidazole.

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It is estimated that only a small percentage of those who suffer from rosacea recognize they have it or that effective medical treatments are available to halt its progression. Beginning usually between the ages of 30 and 50 years, the persistent facial redness, papules and pustules of rosacea are often mistaken for acne or some other complexion problem that is expected to pass. If left untreated, however, the condition usually worsens in an unpredictable and progressive manner, often producing permanent tissue changes such as telangiectasia, tissue fibrosis and rhinophyma.

Early treatment with oral antibiotics and/or topical metronidazole has been shown to be an effective way to treat rosacea and prevent it from worsening. Topical metronidazole 1% cream over eight weeks was shown to be as effective as oral tetracycline (250 mg bid) at reducing papules and pustules in 76 patients with rosacea although the tetracycline had a more rapid effect and achieved more instances of total symptom elimination (1). Chronic treatment with these agents has shown to be effective at preventing relapse but, because of the increased risk of adverse effects with long-term oral antibiotic treatment, topical formulations are preferred whenever possible. In a recent editorial published in the Archives of Dermatology, metronidazole was deemed most valuable as a remission-maintaining agent in rosacea (2).

In a study reported here, researchers found that topical metronidazole gel, 0.75% (MetroGel®, Galderma Canada Inc.) alone was effective at preventing relapse of moderate to severe rosacea following treatment with oral tetracycline in 80% of patients studied. In this double-blind, vehicle-controlled study, 88 subjects who had received successful treatment of rosacea with oral tetracycline in combination with topical metronidazole were randomized to apply either topical metronidazole gel 0.75% (n=44) or topical metronidazole gel vehicle (n=44) twice daily. The age range of the patients was 20-74 years (mean age: 46 years).

Evaluation of rosacea was performed each month for six months. Topical metronidazole gel significantly ( $p<0.05$ ) prolonged the disease-free interval and minimized recurrence compared to subjects treated with vehicle. By the end of the study, more than twice as many subjects in the vehicle group relapsed compared to those applying metronidazole gel ( $p<0.05$ ). The metronidazole-treated group had fewer papules and pustules after six months of treatment ( $p<0.05$ ). Relapse of erythema also occurred less often in subjects treated with metronidazole (74% vs 55%).

Despite the success of the metronidazole gel, 20% of patients in the metronidazole-treated group experienced relapse within the first 12 weeks of the study. Dr. Michael Tuley of Galderma Laboratories, Inc., one of the 17 authors of the study, explained, "We found that roughly 90% of the patients who go on oral tetracycline and topical metronidazole will be significantly improved. Of these patients, 80% are going to be controlled with topical metronidazole alone. However, those patients on vehicle continued to relapse throughout the study. We recently looked at the characteristics of patients who relapsed on topical metronidazole alone. We are trying to help physicians in identifying who will



stay controlled on metronidazole gel and who will relapse. It turns out that there are some definite demographic characteristics in this group which are easily identifiable at baseline. We recently submitted a paper on this which is still under peer review.”

Dr. Neil Shear, head of clinical pharmacology at the University of Toronto, and in practice at Sunnybrook Health Science Centre, said, “Most dermatologists have indicated in surveys that they prefer to start rosacea treatment with oral tetracycline and topical metronidazole together until they get the symptoms under control. After a couple of months, they will stop the tetracycline and continue with the metronidazole. But up until now, we haven’t been able to tell them what to expect. If you look at the data, you see that 20% of the people on topical metronidazole relapsed in the first 12 weeks and 80% didn’t relapse at all.

“Now I can say to my patients, 20% of people will have a relapse on metronidazole over the first three months. If you’re one of them, you may have to consider going back on tetracycline for awhile. On the other hand, if you’re one of the 4 out of 5 who is not going to relapse, the metronidazole will keep you well under control. It’s a lovely study, actually, because it gives me a handle and I can actually give my patients some numbers now.”

Presently, there are three topical formulations of metronidazole available in Canada for the treatment of rosacea: metronidazole gel 0.75% (MetroGel®), metronidazole cream 0.75% (MetroCream™, Galderma Canada Inc.), and metronidazole cream 1% (Noritate®, Dermik Laboratories Canada, Inc.).

Dr. Shear, commenting on the difference between cream and gel formulations, said, “MetroGel® is generally well-tolerated and I think most dermatologists use that first. But in certain parts of the country where the winters are cold and dry, I use cream 80% of the time. Sometimes, I use cream in the winter and gel in the summer. I’ve had some patients who can’t tolerate the gel but really love the cream. It’s important to find the right formulation because they’re going to be using it a long time.”

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References:

1. Veien, N.K., Christiansen J.V., Hjorth N., Schmidt H. Topical Metronidazole in the Treatment of Rosacea. *Cutis* 1986; 38:209-10.
2. Wilken J.K. Rosacea: Pathophysiology and Treatment. *Arch Dermatol* 1994;130:359-362.