

Table 1. Sample Size Needed to Show a 20 Percent Difference in Cure Rates When the Male Sexual Partner Is Treated from a Baseline Cure Rate of 90 Percent in Women with Bacterial Vaginosis, Alpha = 0.05.

Statistical Power	Number of Patients per Treatment Group
0.80	75
0.90	100
0.95	120

metronidazole 500 mg bid.⁸ At least 75 subjects in each group would be needed to achieve even a minimal statistical power (Table 1). Our study, because we could pool male sexual partner treatment groups, is the only study to date that has achieved greater than 80 percent statistical power calculated by a Monte Carlo simulation technique.² It is, therefore, no surprise that we were able to detect a clinically significant difference, while the other study performed in a family practice setting did not. In fact, using the clinically significant 20 percent difference in cure rates, we calculated that our study's statistical power among the single-dose patient treatment groups was 48 percent, and among the 7-day patient treatment groups it was 37 percent. Thus, we would strongly recommend that future studies of male sexual partner treatment possess adequate statistical power so as not to cloud this issue further.

The sample size needed to show a 50 percent difference in recurrence rates is even greater. Using a baseline recurrence rate of 25 percent, the recurrence rate found in one study within 6 weeks after having been judged cured,⁹ the sample size needed to detect a 50 percent difference in recurrence rates ranges from 150 to 259 (Table 2). It is no surprise that the two studies performed in the family practice setting did not find statistically significant differences because they did not contain adequate power. This includes our own study. However, in our study we did find near-significant trends, indicating that if the male sexual partner was treated, women with bacterial vaginosis enjoyed lower recurrence rates,² and we are hopeful that a study with adequate sample size will show that male sexual partner treatment does significantly reduce the high recurrence rates.

In conclusion, we agree with Dr. Quan that "At the present time, it appears reasonable to reserve treatment

Table 2. Sample Size Needed to Show a 50 Percent Difference in Recurrence Rates When the Male Sexual Partner Is Treated from a Baseline Recurrence Rate of 25 Percent in Women with Bacterial Vaginosis, Alpha = 0.05.

Statistical Power	Number of Patients per Treatment Group
0.80	150
0.90	208
0.95	259

of the man partner to instances of recurrent infections in the woman."^{1 p 203} However, we disagree that the area is controversial because of a number of well-designed studies that have shown that male sexual partner treatment has not proved beneficial. The area is controversial because studies simply do not possess adequate statistical power. We would encourage investigators to study this issue further by enrolling enough women with bacterial vaginosis to insure adequate statistical power. Until such studies are performed, this controversy will continue to exist.

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References

1. Quan M. Diagnosis and management of infectious vaginitis. *J Am Board Fam Pract* 1990; 3:195-205.
2. Mengel MB, Berg AO, Weaver CH, et al. The effectiveness of single-dose metronidazole therapy for patients and their partners with bacterial vaginosis. *J Fam Pract* 1989; 28:163-171.
3. Paavonen J, Stamm WE. Sexually transmitted diseases. Lower genital tract infections in women. *Infect Dis Clin North Am* 1987; 1:179-98.
4. Swedberg J, Stinner JF, Deiss F, Steiner S, Driggers DA. Comparison of single-dose vs. one week course of metronidazole for symptomatic bacterial vaginosis. *JAMA* 1985; 254:1046-9.
5. Eschenbach DA, Critchlow CW, Watkins H, et al. A dose-duration study of metronidazole for the treatment of nonspecific vaginosis. *Scand J Infect Dis* 1983; 40(Suppl):73-80.
6. Mengel MB. Bacterial vaginosis. *JAMA* 1986; 255:1707.
7. Davis AB, Mengel MB. A Monte Carlo technique for estimating the statistical power of a log-linear model. *J Fam Pract* 1990; 30:578-84.
8. Weaver CH, Mengel MB. Bacterial Vaginosis. *J Fam Pract* 1988; 27:207-15.
9. Pheiffer TA, Forsyth PS, Durfee MA, et al. Non-specific vaginitis: role of *Haemophilus vaginalis* and treatment with metronidazole. *N Engl J Med* 1978; 298:1429-34.

Nonsedating Antihistamines

To the Editor: I wish to bring to your attention a possible significant calculation error in the recently published comparison study of nonsedating antihistamines by The Clinical Experience Network (October-December 1990). Table 6 on page 246 lists "Totals" for the "Mean Severity Scores" that do not equal the sums of the "Sign-Symptoms." Specifically, the Mean Severity Scores for astemizole are inaccurately calculated for Entry (10.6 listed versus 10.7 by addition) and Final (2.7 listed versus 3.1 by addition). Also, the Mean Severity Score for terfenadine is miscalculated for Final (3.4 listed versus 3.0 by addition). The net effect of these apparent errors is to portray astemizole as being more effective at sign-symptom relief when actually the converse would seem to be true.

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