21. Palmer JM, Link D. Impotence following anesthesia for elective circumcision. JAMA 1979; 24:2635-6.
22. Sara CA, Lowry CJ. A complication of circumcision and dorsal nerve block of the penis. Anaesth Intensive Care 1985; 13:79-82.

The above letter was referred to the authors of the article in question, who offer the following reply.

To the Editor: We commend Ganiats and Schmidt for their detailed MEDLINE literature review. At the same time, some of the findings drawn from their own review of the existing literature seem inconsistent with their conclusions. For example, they describe a "paucity of research" and then reference 19 "appropriate research articles." They conclude that "one large-scale study . . . appears to underreport complications," yet fail to state the basis for this conclusion. They also conclude that the lack of widespread acceptance of dorsal penile nerve block reflects a lack of safety data, yet only 27 percent of the doctors we surveyed stated that they were not using the technique because of a "concern of risk." [1]

The report of two cases of gangrene following dorsal penile nerve block in infants deserves clarification. The technique used was distinctly different from that first described by Kirya and Werthmann and also utilized bupivacaine as the local anesthetic.[2,3] Despite the apparently complete MEDLINE review with 22 references, the authors have excluded work by Stang and Snellman, who reported their experience with dorsal penile nerve block in more than 2000 circumcisions without any clinically significant complications.[4] Ganiats and Schmidt's concern about the potential for future impotence seems unlikely with the clinical observation of postcircumcision erections in babies, whether dorsal penile nerve block is employed or whether it is not. In short, the conclusion that dorsal penile nerve block "has not yet been proved safe" seems inconsistent with the very data that they present, just as it is inconsistent with our own experience.

Additionally, although not impossible, it seems improbable that after 12 years of using this technique nationally, other complications have not surfaced. A conservative estimate of the number of procedures done to date would number in the hundreds of thousands or more. In addition, the procedure has been performed for even longer by anesthesiologists for postoperative anesthesia for circumcision in older persons.

Nevertheless, we agree that further research involving long-term effects is worthwhile to reassure physicians who have persistent serious concerns about possible long-term consequences. In fact, such studies are underway by at least two separate investigators in Minnesota (personal communication). Meanwhile, the procedure clearly decreases the pain associated with circumcision in infants, positively affects the behavior following the procedure, and clearly assuages the guilt that many parents feel when they decide to have their children circumcised and consider the pain that would otherwise result from the procedure.

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References

1. Toffler WL, Sinclair AE, White KA. Dorsal penile nerve block during newborn circumcision: underutilization of a proven technique? J Am Board Fam Pract 1990; 3: 171-4.
2. Kirya C, Werthmann MW, Jr. Neonatal circumcision and penile dorsal nerve block—a painless procedure. J of Pediatr 92:998, 1978.
3. Sara CA, Lowry CJ. A complication of circumcision and dorsal nerve block of the penis. Anesth Inten Care, 1985; 13:79-82.
4. Stang HJ, Snellman L. Dorsal penile nerve block for circumcision [Letter]. JAMA 1989; 261:702.

Infectious Vaginitis

To the Editor: In the article entitled "Diagnosis and Management of Infectious Vaginitis," [1] Dr. Quan states, "Controversy continues to exist whether the man consort(s) of the patient with bacterial vaginosis requires simultaneous treatment." [p 203] Dr. Quan cites our study and correctly indicates that we concluded that treatment of the male partner produces a short-term reduction in recurrence rates. He then references three other reports, which he states were studies that did not report a benefit from male sexual partner treatment.[3-5] Unfortunately, of the three references that Dr. Quan cites, one is a review article that simply says that male sexual partner treatment has not been shown to be effective, and the authors do not provide references.[3] Another is a dose-duration study of metronidazole treatment in patients with bacterial vaginosis, and no data are described about male sexual partner treatment. The other reference, even though it is to a study that examines the issue of male sexual partner treatment, lacks adequate statistical power to conclude that male sexual partner treatment does indeed make no difference in cure rates or recurrence rates.[4,6] Although it seems from Dr. Quan's article that there is only one study that supports the effectiveness of male sexual partner treatment in women with bacterial vaginosis and three against, this is clearly not the case. We believe this is an inaccurate portrayal of this controversial area.

It is controversial because investigators do not enroll enough women in their studies to insure adequate statistical power to find a clinically significant difference in cure rates or recurrence rates, should it indeed exist. We think that clinicians would pay attention to a 20 percent difference in cure rates between a group in which the male sexual partner was treated versus not treated[7] and have calculated the number needed in each group at various statistical powers, from a minimal power of 0.80 to a maximal power of 0.95, using a baseline cure rate of 90 percent, which is the baseline cure rate found in most studies if the woman is treated with a 7-day course of

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 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.

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

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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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