A Patient's Guide to Managed Care in the House of God: The Best Care Is Less Care

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Managed care and managed competition are sweeping the country. Virtually every aspect of health care is being viewed as amenable to economic rationalization through the use of managed business techniques. Under the rubric of containing health care costs, medical decision-making is increasingly shifting from control by physicians to control by insurance companies subject to "market forces." This new age of managed medicine is bringing colorful and exciting developments to a system that is, as most would agree, in need of reform. Some of the more notable sequelae of market-driven health care include a frenzy of health care corporation takeovers reminiscent of Wall Street in the 1980s, $7 million paychecks for CEOs of managed care organizations,[1] and insurers' micromanagement of the physician-patient relationship.

The American Medical Association recently raised ethical concerns about the integrity of the physician-patient relationship in managed care settings. Business-imposed pressures for physicians to see more patients, prescribe fewer tests and treatments, and make fewer referrals could lead to the inability of physicians to act in their patients' best interests and ultimately to a destruction of the physician-patient relationship.[2] Knowledgeable professionals predict that, in spite of these concerns, managed care is inevitable and will soon be ubiquitous. Therefore, physicians and ethicists should stop whining about the loss of the doctor-patient relationship.

The question we should ask is not "How can we preserve the physician-patient relationship under managed care?" but "How can we teach patients to accept a different relationship with their physicians, one that reflects the current health business environment rather than archaic, sentimental values of trust and integrity?" The challenge for us now is to help patients accept the realities of market medicine and encourage them to quit romanticizing about physicians who talk to patients, advocate for them, or engage in other such nonreimbursable nonsense.

The following Laws of Managed Care have been developed at that microcosm of American medicine, the House of God[3] where, in keeping with current medical economic trends, the House of God HMO has recently been established. These laws are offered as a public service, with the goal of assisting physicians in educating their patients and promoting their acceptance of or resignation to the managed care philosophy.

- **Law No. 1:** *There is no such thing as an "individual patient."* You are a "statistical patient" and will be treated (or not treated) according to your insurer's preestablished calculations of what tests and treatments can be provided to all its "covered lives" within a framework of profit.
- **Law No. 2:** *There is no such thing as a "complete physical."* On a routine visit, you will receive an incomplete physical examination, which will be euphemistically referred to as a "health check" or "wellness exam." On a problem-oriented visit, only the affected body part will be examined, if time allows.
- **Law No. 3:** *Don't ask, don't tell.* This refers to physician-patient communication, not to your sexual orientation. Your doctor will be required to see a quota of patients, usually in 15-minute slots. During the first 10 minutes, while the doctor reviews your medical record, you will be in the waiting room filling out a medical history form that will never be mentioned again. Forty-five seconds will be allowed for an assistant to escort you to an examination room and for you to put on a gown. The physical examination will take approximately 2½ minutes. One minute and forty-five seconds remains for your physician to provide a diagnosis and plan. Managed care etiquette requires that you and your physician respect this time limit. Therefore, you will not ask questions

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and your physician will not engage in frivolous chatter involving explanations or reassurance. If you want these, contact your local naturopath.

- **Law No. 4:** *Doctors and nurses are no longer "doctors and nurses."* They are "health care providers." A corollary of this law is "There is no such thing as 'calling the doctor' when you become ill." You now call the gatekeeper, who is usually a triage nurse. She will decide whether you will see your doctor and, in some cases, whether your doctor will be reimbursed for services provided. Whether you will be seen by a health care provider depends on the conditions listed in Law No. 5.
- **Law No. 5:** *Your chances of actually seeing a "health care provider" depend on type of health care coverage, not on type or severity of symptoms.* In a plan that reimburses for individual procedures, you will be seen or admitted for the sniffles if clinic slots or hospital bed spaces are available. If no slots or bed spaces are available, you will be given instructions on how to treat your pneumonia at home. If you belong to a capitated plan, decisions will be made using a "best interests" standard—the plan's best interests, that is. In the latter case, the gatekeeper will provide the market medicine version of sympathy and treatment advice over the phone: "Everyone has the flu nowadays; call us if you develop chest pain."
- **Law No. 6:** *Getting to know your health care provider is detrimental to the provider-patient transaction.* There are two reasons for this. (1) Given the amount of time you spend with your physician, you may not remember his or her face or name. This may work to your advantage if something goes wrong: it is always easier to sue someone you don't know. (2) If you should find an old-fashioned physician who answers questions and listens to your concerns, and who provides reassurance and appropriate care based on your medical needs, this doctor most likely will not be employed by your health plan next year.

Patients, or rather clients, should not view the loss of a relationship with their physician negatively. The philosophy of most managed care plans is "the best care is less care." Managed care will help us to become more self-reliant in caring for ourselves. The sociologist Ivan Illich once decried what he called "cultural iatrogenesis,"[4] a condition of our becoming dependent on professionals to take care of ourselves rather than having the confidence to solve our own health care problems. Managed care provides us with the opportunity to become more self-sufficient in meeting our health care needs while keeping costs down and insurers' profits up. Under managed care, patients can learn to deal with their illnesses proactively in several ways:

- *Get to know your medical library.* Better yet, ask a former Peace Corps volunteer to lend you her copy of a book entitled *Where There Is No Doctor.*[5] Everyone can pitch in and help solve the "access problem" by learning to treat their own minor illnesses. China has its barefoot doctors; now every American can become a junior practitioner. Networks will evolve for the exchange of information and black market medications.
- *Remember that most illnesses are self-limiting.* Your problem will, in most instances, go away eventually whether you treat it with a prescription drug, burn a little incense, or do nothing at all. Besides, suffering is good. Many religions value suffering, and some people believe that it helps build character, especially in children. Managed care will actually help improve the moral fiber of our country.
- *Know which buttons to push if all of the above fails and you really do need to see a doctor.* A complaint of chest pain usually is your ticket to immediate access to a physician, but be sure to describe it to the triage nurse as "crushing" and "going down my left arm." A "fever of 103° for the past 2 days" also may help you gain access to a health care provider, while a fever of 101° may result only in a recommendation of acetaminophen.

Patients who learn the Laws of Managed Care, acquire techniques for self-care, and resign themselves to the system will benefit in several ways. Lower patient expectations will increase patient satisfaction, and increased satisfaction will result in decreased stress. Best of all, managed care patients will help reaffirm American cultural values of self-reliance, strength of character, and the worth of a dollar, especially when it applies to health care.

Author's Note

With apologies to Samuel Shem, MD, PhD, and to my own competent and caring health care providers.

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Treatment of Bacterial Vaginosis: A Comparison of Oral Metronidazole, Metronidazole Vaginal Gel, and Clindamycin Vaginal Cream

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Background. Treatment options for bacterial vaginosis are numerous. The purpose of this study was to compare the efficacy of oral metronidazole, metronidazole vaginal gel, and clindamycin vaginal cream for the treatment of bacterial vaginosis using traditional clinical and laboratory methods, as well as a new DNA probe test. We also determined the percentage of patients receiving each treatment who developed posttreatment vaginal candidiasis, a potential complication of treating bacterial vaginosis.

Methods. One hundred one women in whom bacterial vaginosis was diagnosed by standard criteria were randomly assigned to receive: oral metronidazole 500 mg twice daily for 1 week, 0.75% metronidazole vaginal gel 5 g twice daily for 5 days, or 2% clindamycin vaginal cream 5 g once daily for 7 days. Women with coexisting vulvovaginal candidiasis or vaginal trichomoniasis were excluded. Tests of cure by vaginal saline wet prep and potassium hydroxide microscopic examinations, Gram's stain, pH and DNA probe tests for *Gardnerella vaginalis* and *Candida* species were scheduled 7 to 14 days following treatment.

Results. There were no statistically significant differences in cure rates for oral metronidazole (84.2%), metronidazole vaginal gel (75.0%), or clindamycin vaginal cream (86.2%) (χ^2=1.204, *df*=2, *P*=.548) using traditional clinical and laboratory criteria. Cure rates were lower based on DNA testing, indicating that *Gardnerella vaginalis* may remain after a clinical cure. This would explain cases of recurrent disease. Posttreatment vulvovaginal candidiasis was experienced by 12.5% of subjects treated with oral metronidazole, 14.8% of subjects treated with clindamycin vaginal cream, and 30.4% of subjects treated with metronidazole vaginal gel (χ^2=2.607, *df*=2, *P*=.272).

Conclusions. Oral metronidazole, metronidazole vaginal gel, and clindamycin vaginal cream achieved nearly equivalent cure rates for the treatment of bacterial vaginosis. Patients treated with these agents experienced similar rates of posttreatment vulvovaginal candidiasis, but those using the intravaginal products reported being more satisfied with the treatment.

Key words. Vaginosis, bacterial; metronidazole; clindamycin; *Gardnerella vaginalis; Candida.* (*J Fam Pract 1995; 41:443-449*)

Bacterial vaginosis is the most common type of vaginal infection among young women.[1] The condition represents an alteration of the normal *Lactobacillus*-mediated vaginal ecosystem.[2] A multitude of microorganisms, *Gardnerella vaginalis, Mycoplasma hominis, Bacteroides, Mobiluncas*, and other anaerobic bacteria, have been implicated as the causative agents responsible for this noninflammatory vaginal infection.[3-5] In addition to the sometimes offensive vaginal discharge,[6] bacterial vaginosis has been identified as a risk factor for preterm birth[7] and postsurgical infections.[8-11] Because bacterial vagino-

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sis represents a complex polymicrobial ecosystem alteration, specific laboratory diagnosis and definition of cure are problematic. It is unreliable to base a diagnosis of bacterial vaginosis on a single laboratory value or clinical sign. Using the criteria of Amsel et al,[12] the classic diagnosis is indicated by the presence of three of the four following findings: (1) clinical evidence of an off-white creamy adherent vaginal discharge, (2) a vaginal pH greater than 4.5, (3) microscopic evidence of clue cells (squamous epithelial cells coated by bacteria), and (4) a positive amine "sniff" test (a release of odoriferous volatile amines from an alkalinized vaginal specimen).[12]

The Centers for Disease Control and Prevention currently recommends several treatment options for bacterial vaginosis: metronidazole 500 mg orally twice daily for 7 days; metronidazole 2 g orally twice; clindamycin 300 mg orally twice daily for 7 days; 2% clindamycin vaginal cream 5 g once daily for 7 days; and 0.75% metronidazole vaginal gel 5 g twice daily for 5 days.[13] Although none of these treatment options is ideal in all circumstances, the short-term cure rates appear similar.[3–5,14–17]

The 7-day oral metronidazole regimen has been extensively evaluated in many trials.[3,14,16] The two newest treatment options, both topical vaginal medications,[4,5,17] deliver high drug concentrations to the site of infection while simultaneously minimizing systemic absorption. These intravaginal approaches have not been as extensively studied[18] or simultaneously compared. Their efficacy has been established by symptom resolution, safety profile, and by laboratory testing with vaginal wet prep, pH determination, amine test, Gram's stain, and vaginal culture. No previous study has used testing for *G vaginalis* by DNA probe technology.

The purpose of this study was to compare the efficacy and treatment complications of oral metronidazole, metronidazole vaginal gel, and clindamycin vaginal cream for the treatment of bacterial vaginosis using traditional and newer DNA probe testing for evaluation of therapeutic response.

Methods

Women were recruited from three clinics, the Family Medicine Center and Student Health Center at The Medical College of Georgia, and the Richmond County Health Department, Augusta, Georgia. Women 15 years of age or older who had symptoms of a vaginal infection (an abnormal or increased vaginal discharge, itching, irritation, or odor) and a clinical or laboratory diagnosis of bacterial vaginosis were enrolled in the study. Bacterial vaginosis was defined as the presence of clue cells in a vaginal specimen and at least two of the following findings: a vaginal discharge, vaginal specimen pH greater than 4.5, or a positive amine test following the addition of 10% potassium hydroxide (KOH) to the specimen.[12] Bacterial vaginosis was also defined as a positive DNA probe test result for *G vaginalis* (Affirm VPIII, MicroProbe, Bothell, Wash) and a pH greater than 4.5.[19] The exclusion criterion was a history of hypersensitivity to metronidazole, parabens, propylene glycol, clindamycin, or mineral oil. Nursing mothers, pregnant women, patients treated for a vaginal infection within 14 days of enrollment, those with coexisting vulvovaginal candidiasis or vaginal trichomoniasis, and patients receiving lithium, anticoagulant therapy, or disulfiram were excluded. Patients with a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis were also excluded from the study. Women treated with metronidazole were told to abstain from alcohol ingestion during the treatment phase of the study. Subjects were also encouraged to abstain from sexual intercourse, douching, and using intravaginal products until after the follow-up visit.

Subjects were asked to volunteer for the study if their condition was diagnosed as bacterial vaginosis. The purpose of the study and their involvement was explained to each subject and each gave informed consent.

Following visualization of the vagina with a vaginal speculum, the lateral vaginal walls and adherent discharge were sampled using three swabs. The first swab was placed into a tube containing several drops of normal saline for saline and KOH microscopic examination. The second specimen swab was rolled onto a glass slide for Gram's stain and then rolled across pH paper to determine the vaginal pH. Care was taken to avoid sampling the cervical os, mucus, and the posterior vaginal fornix. The third swab was used to obtain a specimen for DNA testing. Subjects determined to have bacterial vaginosis by the criteria of Amsel and co-workers,[12] or by a positive DNA probe test for *G vaginalis* plus a pH greater than 4.5,[19] were considered eligible for treatment.

Subjects were randomly assigned to one of the three treatment groups, either oral metronidazole 500 mg twice a day for 1 week, or 0.75% metronidazole vaginal gel (Curatek Pharmaceuticals, Elk Grove Village, Ill) 5 g twice a day for 5 days, or 2% clindamycin phosphate vaginal cream (Upjohn Pharmaceutical Company, Kalamazoo, Mich) 5 g once a day for 7 days. Subjects were given a drug diary log to record each dose, written instructions and illustrations of proper drug dosing, and a return appointment for follow-up testing.

Subjects were asked to return 7 to 14 days after initiation of treatment for questioning, reexamination, and vaginal specimen testing. Treatment compliance was verified verbally and by review of the drug diary log. A questionnaire including a 5-point Likert-type scale was used to record each patient's satisfaction with her respec-

tive medication. Persistent vaginal symptoms, complications, side effects, and general comments were noted. A brief vaginal examination was performed, and vaginal specimens were obtained for test-of-cure analyses. The same diagnostic tests as those performed initially were then processed. Clinical treatment failure was defined as the persistence of two of the following: clue cells, a creamy adherent vaginal discharge, pH greater than 4.5, or a positive amine test. DNA treatment failure was defined as a positive DNA probe test for *G vaginalis* plus a pH greater than 4.5.

The DNA probe test is a combination of nucleic acid probes for the detection of *G vaginalis, Trichomonas vaginalis*, and *Candida* species. A trained and proficient medical technician prepared and processed the test and interpreted the results per the manufacturer's protocol in a fashion similar to methods previously described.[20,21] Vulvovaginal candidiasis by DNA was defined as the presence of a blue color on the PAC for *Candida* species.

The saline wet mount was prepared by combining a small amount of vaginal discharge specimen with one drop of normal saline, covering it with a cover slip, and examining it by light microscope for the presence of clue cells, trichomonads (motile protozoan organisms with flagella), pseudohyphae, leukocytes, and *Lactobacillus* sp.

The KOH test was performed by combining a small vaginal specimen with 10% KOH on a glass slide. The fluid was immediately evaluated for the presence of a fishy odor indicative of a positive amine or "sniff" test result. A cover slip was positioned and the specimen was then examined for fungal elements under high power of the light microscope. The presence of pseudohyphae or buds defined vulvovaginal candidiasis.

The pH determination was made following the application of the vaginal discharge specimen on pH paper (MicroEssential Laboratory, Inc, Brooklyn, NY) with a pH range of 3.0 to 5.5. The resulting colormetric reaction was compared with the corresponding pH reference scale to determine the vaginal pH.

The Gram's stain was prepared by rolling a small amount of vaginal specimen on a glass slide, heat-fixing, and then processing by the Gram's stain technique. A medical technician and a medical technologist independently interpreted the smears for the presence of microorganisms, clue cells, trichomonads, and pseudohyphae. Discordant interpretations were adjudicated by a third individual. The Gram's stain definition of bacterial vaginosis was the presence of squamous epithelial cells covered by adherent bacteria.

The proportion of cured subjects was compared between treatment groups by the chi-square test. For contingency tables with cells having expected counts of less than 5, the likelihood ratio chi-square statistic was used for tables larger than 2 × 2 and Fisher's exact test was used for 2 × 2 tables. Each subject's symptoms at the beginning and follow-up of the study were compared using the McNemar's test. Mean age of subjects was compared between treatment groups by analysis of variance. The time interval from treatment initiation to follow-up was compared between groups using the Kruskal-Wallis test.

Results

One hundred one women were enrolled and randomized to receive one of three pharmaceutical agents. Twelve subjects failed to return for the test-of-cure visit, two subjects took their medication inappropriately, one subject discontinued the medication because of an allergic reaction, two subjects discontinued the medication for medical reasons, and two subjects discontinued medication because of pregnancy. Seven subjects reported no symptoms at the beginning of the study. Three subjects who had been initially enrolled by clinicians were later excluded from the data analysis because of coexisting vulvovaginal candidiasis or vaginal trichomoniasis discovered after confirmatory microscopic examination by the medical technician. Seventy-two subjects were considered evaluable: 19 treated with oral metronidazole, 24 treated with metronidazole vaginal gel, and 29 treated with clindamycin vaginal cream. There was no statistically significant difference in the proportion of subjects who completed therapy among the three cohorts (χ^2=4.516, df=2, P=.105).

The mean age of subjects was 28.6 (standard deviation [SD]=9.135) years with a range of 15 to 60 years. The three treatment groups did not differ significantly with regard to age, history of bacterial vaginosis, vulvovaginal candidiasis or vaginal trichomoniasis, presenting vaginal symptoms (itching, irritation, odor, abnormal discharge, or increased discharge), or study compliance.

The cure rates were 86.2% for clindamycin vaginal cream, 75.0% for metronidazole vaginal gel, and 84.2% for oral metronidazole. As shown in Table 1, the three medications did not differ significantly in clinical cure rate (Amsel's criteria) (P=.548), Gram's stain cure rate (P=.168), or DNA criteria for cure (P=.823). The effective cure rates were lower when based on Gram's stain criteria and even lower when based on DNA and pH criteria. The mean interval from treatment initiation to test of cure was 24.5 days for oral metronidazole, 20.0 days for metronidazole vaginal gel, and 26.6 days for clindamycin vaginal cream (P=.125).

Several bacterial vaginosis signs and symptoms resolved or improved following treatment (Table 2). There were significant improvements in clinician-observed and

Table 1. Efficacy of Treatment of Bacterial Vaginosis (N = 72)

Medication	Cure Rate As Determined by			
	Amsel's Criteria	Gram's Stain	DNA plus pH*	Office Microscopic Examination†
Oral metronidazole, n/total (%)	16/19 (84.2)	11/19 (57.9)	10/18 (55.6)	12/19 (63.2)
95% CI	60.4, 96.6	33.5, 79.7	30.8, 78.5	38.4, 83.7
Metronidazole vaginal gel, n/total (%)	18/24 (75.0)	17/24 (70.8)	14/24 (58.3)	18/24 (75.0)
95% CI	53.3, 90.2	48.9, 87.4	36.6, 77.9	53.3, 90.2
Clindamycin vaginal cream, n/total (%)	25/29 (86.2)	24/29 (82.8)	18/28 (64.3)	25/29 (86.2)
95% CI	68.3, 96.1	64.2, 94.2	44.1, 81.4	68.3, 96.1
χ^2 (df=2)	1.204	3.572	0.390	3.420
P Value	NS	NS	NS	NS

**Positive DNA probe test result for* Gardnerella vaginalis *and vaginal pH>4.5.*
†Diagnosis by medical technician's saline wet prep examination.
NOTE: Percentages represent available responses.
CI denotes confidence interval.

patient-observed vaginal discharge for women treated with oral metronidazole and clindamycin vaginal cream. A significant reduction in clue cells and amine odor detected by the laboratory technician was noted for all three medications. There was also a significant resolution of overall symptoms noted in all three cohorts following treatment. No significant differences were observed in the reported vaginal pH or in the symptoms of itching, irritation, or patient-reported odor after therapy with any of the three medications analyzed separately. When the medications were jointly considered, however, significant improvement in all clinical signs and symptoms except for vaginal pH were observed following treatment (Table 3).

Few adverse side effects were encountered by subjects during the study. Posttreatment vulvovaginal candidiasis was noted in 12.5% of subjects treated with oral metronidazole, 14.8% of subjects treated with clindamycin vaginal cream, and 30.4% of subjects treated with metronidazole vaginal gel based on KOH microscopic examination. These differences, however, were not statistically significant. One subject experienced an allergic reaction to metronidazole vaginal gel, and many subjects complained that oral metronidazole tasted bad. Although most subjects were satisfied with their medication (Figure), a greater percentage of subjects were "very satisfied" or "extremely satisfied" with the two intravaginal products.

Conclusions

Many antibiotics have been shown to be ineffective for treating bacterial vaginosis.[22–24] This clinical investigation

Table 2. Effect of Each Treatment on Bacterial Vaginosis Signs and Symptoms

Signs/Symptoms	Oral Metronidazole (n = 19)		Metronidazole Vaginal Gel (n = 24)		Clindamycin Vaginal Cream (n = 29)	
	Initial	Follow-up	Initial	Follow-up	Initial	Follow-up
Signs, %						
Clinical discharge	88.9	22.2*	87.5	62.5	95.7	52.2*
Clue cells	97.7	42.1*	83.3	29.2*	86.2	17.2*
pH>4.5	100.0	94.4	91.3	78.3	96.3	92.6
Amine odor	52.9	17.7	52.2	17.4*	42.3	0.0*
Symptoms, %						
No symptoms	5.3	68.4*	13.0	43.5†	10.3	72.4*
Itching	31.6	15.8	34.8	26.1	31.0	13.8
Irritation	31.6	15.8	39.1	13.0	24.1	6.9
Odor	36.8	10.5	17.4	17.4	24.1	6.9
Abnormal discharge	78.9	26.3*	52.2	43.5	72.4	13.8*
Increased discharge	21.1	5.3	30.4	8.7	24.1	6.9

**Comparison of initial and follow-up results by McNemar's test for each medication, P<.01.*
†Comparison of initial and follow-up results by McNemar's test for each medication, P<.05.

Table 3. Effect of Combined Treatments on Bacterial Vaginosis Signs and Symptoms (n = 72)

Signs/Symptoms	Initial Visit	Follow-up Visit	χ^2	*P* Value
Signs, %				
Clinical discharge	91.2	45.6	22.32	<.001
Clue cells	87.5	27.8	39.20	<.001
Vaginal pH > 4.5	95.6	88.2	1.78	NS
Amine odor	48.5	10.6	21.33	<.001
Symptoms, %				
No symptoms	9.9	62.0	19.11	<.001
Itching	32.4	18.3	4.50	.034
Irritation	31.0	11.3	7.68	.006
Odor	25.4	11.3	4.05	.044
Abnormal discharge	67.6	26.8	20.10	<.001
Increased discharge	25.4	7.0	8.47	.004

evaluated three of the five currently recommended treatment options.[13] Valid therapeutic efficacy measures are contingent on a reliable confirmation test for bacterial vaginosis. Vaginal cultures do not adequately reflect the offending polymicrobial and vaginal ecosystem imbalance.[6,12] Obviously, patient symptoms should be considered when evaluating the outcome of treatment for bacterial vaginosis. The present study considered subjects' symptoms and three different criteria for the diagnosis of bacterial vaginosis: Amsel's criteria,[12] Gram's stain, and DNA evidence of *G vaginalis*. Regardless of outcome measure used, there was no significant difference among cure rates for clindamycin vaginal cream, metronidazole

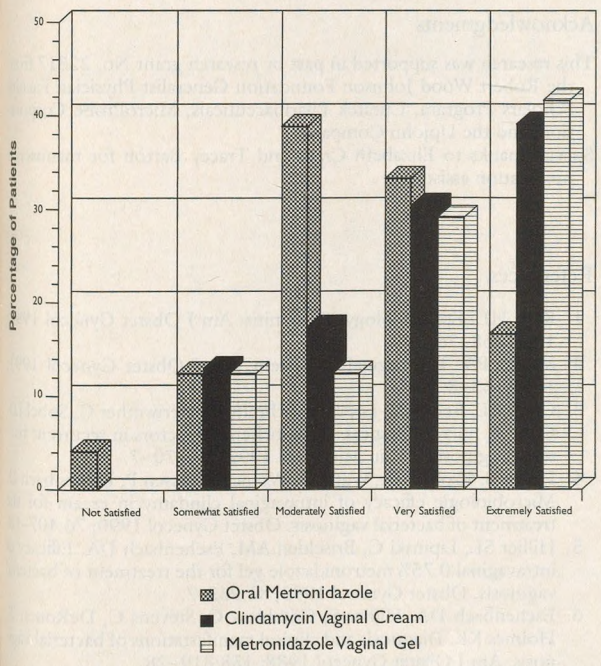

Figure. Subject satisfaction with bacterial vaginosis treatment.

Table 4. Therapeutic Efficacy for Treatment of Bacterial Vaginosis

Medication	Investigators (Publication Year)	Cure rate, %
Clindamycin vaginal cream	Schmitt et al[17] (1992)	72
	Stein et al[25] (1993)	77
	Fischbach et al[26] (1993)	83
	Current study (1995)	86
	Hillier et al[4] (1990)	94
Metronidazole vaginal gel	Current study (1995)	75
	Livengood et al[27] (1994)	78
	Hillier et al[5] (1993)	87
Oral metronidazole	Current study (1995)	84
	Schmitt et al[17] (1992)	87
	Greaves et al[16] (1988)	96
	Swedberg et al[14] (1985)	97

vaginal gel, and oral metronidazole. The magnitude of these cure rates is supported by the evidence that only 18% of subjects continued to have symptoms following therapy (itching 18%, irritation 11%, odor 11%, abnormal discharge 27%, and increased discharge 7%). Our reported cure rates are also similar to those reported previously (Table 4). The spectrum of cure rates reported in the literature may be explained by varied definitions of bacterial vaginosis and its cure.

Three of Amsel's criteria (clinical discharge, clue cells, and amine odor) are excellent measures of cure. The results of our study confirm the traditionally held view of the vaginal pH test as the most sensitive test for the diagnosis of bacterial vaginosis. However, the vaginal pH appeared to function poorly as a test of cure (Table 3). Improper specimen collection may have explained the unexpected persistence of vaginal pH levels greater than 4.5. Sampling of cervical mucus or blood, instead of the vaginal sidewalls, will yield pH results in excess of 5.5, the upper limit of our pH paper. Other researchers have reported a significant return of vaginal pH to normal values following treatment of bacterial vaginosis.[5,14] Alternatively, Cook et al[3] have demonstrated that women with bacterial vaginosis have evidence of a mild persistent elevation of vaginal pH and a small number of clue cells following effective treatment.

Successful treatment of bacterial vaginosis may pose risks for developing secondary vulvovaginal candidiasis. A significant number of women in this study (12.5% to 30.4%) developed posttreatment vulvovaginal candidiasis as evidenced by KOH examination. These moderate rates of infection are consistent with the 20% to 24% rates of posttreatment vulvovaginal candidiasis reported for all three drugs by other authors.[4,5,17] The complication rates for posttreatment vulvovaginal candidiasis were compara-

ble regardless of whether the bacterial vaginosis therapy was administered orally or intravaginally.

In general, a greater percentage of women using the two intravaginal products reported being very or extremely satisfied with the therapy they received than did those using oral metronidazole (Figure). The most common negative comment reported by 13% of women was that oral metronidazole tasted bad. Higher rates (35% to 47%) for dislike of oral metronidazole taste have been reported.[14,17] The lower response to our open-ended question probably reflects the opinions of women who were notably influenced by the metallic taste rather than those of women who, when asked, agreed that the taste was less than pleasant. The most common positive unsolicited comment from 11% of women was that they liked the intravaginal products.

This study is one of the first to use a new DNA test for *G vaginalis*.[20] The DNA test has been shown to detect 90% of women with clue cells on vaginal saline wet-mount examination.[20] The *G vaginalis* DNA test threshold distinguishes asymptomatic women from symptomatic women experiencing bacterial vaginosis. The combination of the DNA probe test result for *G vaginalis* with a vaginal pH determination enables a more accurate detection of an alteration of the vaginal ecosystem. The combined DNA and pH measure demonstrated lower cure rates than those obtained by Gram's stain and Amsel's criteria. The lower cure rates reported by the combined DNA and pH measure may reflect the ability of the DNA test to detect lingering nonviable *G vaginalis* organisms. The lag time between the presence of viable and that of nonviable organisms in the lower genital tract following treatment has been described for *Chlamydia trachomatis*[28] but not for vaginal microorganisms. A similar persistent elevation of vaginal pH following treatment has been described in women with recurrent bacterial vaginosis infections.[3] The delayed reestablishment of *Lactobacillus* organisms and the subsequent generation of lactic acid also influence lower cure rates than those depicted by Gram's stain (a strictly microbiologic assessment) and Amsel's criteria (a nondependent assessment of a normal vaginal ecosystem in relation to pH).

The lower cure rates based on combined DNA and pH testing could also reflect the recurrent nature of bacterial vaginosis,[29] a lingering low-level asymptomatic infection not detected by traditional methods. Mean post-treatment Gram's stain scores have been shown to be better for women with sustained cure for bacterial vaginosis following treatment than for women who develop recurrent bacterial vaginosis 1 month after treatment with intravaginal metronidazole.[27] The continued moderate elevation of vaginal pH also supports the thought that many of these women were incompletely cured as evidenced by indices other than Amsel's criteria. Cook et al[3] demonstrated residual laboratory abnormalities in more than 70% of women treated for recurrent bacterial vaginosis. A failure to establish the normal *Lactobacillus*-mediated vaginal ecosystem following treatment may be a reason for relapse.[6] It is unknown whether women with positive DNA tests are more likely to have a recurrence of bacterial vaginosis following treatment than women who have negative DNA tests after treatment. Yet, this observation may offer an additional clue to as why so many women with bacterial vaginosis have frequent recurrences.

We have reported the first comparative trial of the three most common contemporary pharmaceutical agents used for the treatment of bacterial vaginosis. However, there are several limitations of this study. First, although comparable in size to those reported by others,[3–5,14,17] not all subjects completed therapy. Furthermore, although there was no statistically significant difference among cure rates for the three pharmaceutical agents, the possibility of a beta error exists because of the small sample size. The power of this study to detect a small to moderate effect at $\alpha = .05$ was approximately 40%. Finally, this investigation did not consider long-term cure rates reported by other authors.[3–5,14,17] It would generally be expected that longer duration of follow-up testing would correspond with increasing failure rates. Long-term failure rates have been reported previously for all three medications.[3–5,14,17]

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