

Compliance With Acute Otitis Media Treatment

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A total of 295 patients at four offices were studied to determine whether the type of medical office or population serviced, written instructions given to the patient, or patient familiarity with the prescribing physician influenced compliance with a 10-day course of antibiotics prescribed for acute otitis media. The relationship between compliance with the recommended treatment and outcome was subsequently determined. The study population included all patients with a new case of acute otitis media who presented to any of four different types of family practice centers involved in the study. Results indicated that compliance, as measured by follow-up rates in less than 11 days and urine antibiotic assays, varied significantly between different office types and patient populations. Written instructions did not improve compliance. In the low socioeconomic group, compliance was improved when the patients were diagnosed and treated by their own physicians. Neither the study factors nor compliance was related to outcome.

Physicians need two critical pieces of information to evaluate their therapies—compliance and outcome. Compliance can be defined as the extent to which a person's behavior (in terms of taking medications, following diets, or making life-style changes) coincides with medical advice.¹

The degree of compliance with short-term regimens has been evaluated in several studies. Berg-

man and Werner² studied compliance in 59 children treated for streptococcal pharyngitis with a 10-day course of penicillin. They found penicillin in the urine in less than 50 percent of the patients at 3 days, less than 31 percent at 6 days, and 8 percent at 9 days. Later studies revealed compliance levels with short-term antibiotic regimens documented by urinary assays ranging from 56 percent to 89 percent.³⁻⁷ The reasons for the variation in these results may be secondary to marked differences in the study population (age, ethnicity, and socioeconomic status, among other variables), the study design, and the degree to which patients were aware of the study.

Two studies to date suggest that compliance with taking prescribed medications is increased

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when instructions are given in a written form. Sharpe and Mikeal⁸ found an increase in medication compliance when written instructions, along with an information sheet, were given at the pharmacy to those patients prescribed short-term antibiotics. Colcher and Bass³ found that oral instructions about the disease, plus a written handout, were useful in increasing compliance with a 10-day course of penicillin for streptococcal pharyngitis. They also evaluated outcome by repeat pharyngeal cultures at 9 days, 3 weeks, and 6 weeks. While no difference in culture results was found at 9 days, the low-compliance group did show an increased rate of recurrence at the 3- and 6-week checks.

For a variety of reasons, the physician prescribing a course of antibiotics may not be the patient's usual physician. One study by Charney et al⁴ found that compliance was improved when patients were diagnosed by their own physician for otitis media ($P < .01$) but not when pharyngitis was the diagnosis ($P = .80$).

Acute otitis media (AOM) is an important medical entity in terms of frequency, morbidity, and cost to society. It is second only to upper respiratory tract infections as the most common organic disease in children. By the age of one year, one half of all children have had one case of otitis media, and one tenth have had more than three cases.¹ By three years of age, these figures increase to two thirds and one third of children who have had greater than one and three cases, respectively.⁹ Approximately \$2 billion is spent annually on medical and surgical treatment of otitis media in the United States.¹⁰

Despite its prominent position in primary care, consensus on the diagnosis and treatment of acute otitis media has not been reached. Diagnosis varies from observer to observer depending on the criteria used, the experience of the observer, and the diagnostic armamentarium (eg, pneumatic otoscopy, tympanograms, myringotomies) available. In addition, treatment of otitis media has continued to be controversial over the years, as evidenced by numerous articles discussing whether to treat this condition, and if so, with what, and for how long.^{10,11} Finally, the definitions and evaluations of outcome—cure, recurrence, sequelae—have varied dramatically from study to study.

This study was designed to evaluate three fac-

tors that may influence compliance in the treatment of acute otitis media. Four centers participated in the study to better evaluate whether different office types and populations served have varying compliance rates. The effect of written instructions on compliance was the second factor evaluated. Third, the suggestion that patients comply better when they see their own physician indicates that different follow-up may be necessary to improve compliance when an unfamiliar physician prescribes the treatment. Therefore, the correlation between compliance and familiarity of the physician was examined. Finally, outcome was studied to test correlations between compliance and outcome.

Methods

The study population was derived from patients of four family practice centers participating in the study. These offices consisted of (1) a government-subsidized center staffed by 2 family physicians, 1 family practice fellow, 1 pediatrician, 5 family practice residents, and 3 physician assistants; (2) a community hospital-affiliated family practice center staffed by 2 family physicians and 12 family practice residents; (3) the Family Practice Center at the University of Utah Medical Center, staffed by 5 family practice faculty members, 2 family practice fellows, and 13 family practice residents; and (4) a private practice, consisting of 2 family physicians, in Salt Lake County.

All patients with the diagnosis of acute otitis media were eligible for admission to this study if they had not had that diagnosis in the one month prior to the study period. The diagnosis of acute otitis media was made using each physician's usual criteria. At the time of the diagnosis, the provider completed a data collection form and prescribed a 10-day course of amoxicillin (30 mg/kg/d), or erythromycin and sulfisoxazole (50 mg and 150 mg/kg/d) if the patient was allergic to penicillin. An envelope containing a partially completed prescription blank was attached to each data form for convenience. Written instructions (concerning diagnosis, treatment, and follow-up) were placed in one half of these envelopes as

determined by a random numbers table. If written instructions were included in the envelope attached to the data form, the physician gave the instructions to the patients with the suggestion to read them carefully. The physician's routine oral instructions were given regardless of whether written instructions were included. The patient was encouraged to return to the office in seven days.

A large number of patients at the government-subsidized office spoke Spanish only. Therefore, forms with written instructions in Spanish were available at that office.

At the follow-up visit, data were collected to evaluate compliance and outcome. A urine sample for antibiotic assay was obtained from the patient. The patient was re-examined by the physician, who then gave a disposition of "normal examination," "improved examination," or "not improved." If the patient was not improved, a different antibiotic was prescribed or a referral to an otolaryngologist was made. At each visit, a follow-up form was completed. This form recorded compliance as indicated by the patient or parent, the presence of symptoms, and a description of the physical examination. Follow-up was scheduled at weekly intervals until the condition had improved, and at three-week intervals after improvement was noted until examination results were normal.

If at any time after the initial visit hearing was felt to be impaired according to the parent or patient, an audiogram was scheduled. If the patient failed to return at the one-week check, the patient was telephoned by the receptionist to encourage follow-up. No further prompting was done.

The compliance measurements included whether the patient returned for follow-up within 11 days and whether the urine assay was positive at the first return visit. The outcome measurements consisted of the number of days until the diagnosis of "normal middle ear" was given, the final diagnosis at the last visit for which the patient returned, and the incidence of recurrences within the five-month study period.

The *Sarcina lutea* assay for presence of antibiotic in urine, as described by Charney et al⁴ and adapted from Grove and Randall's original description,¹² and used at the seven-day visit. This test has been shown to provide a more objective estimate of compliance than oral reports or pill counts.²⁻⁴ This assay was standardized and was

then taught to medical assistants at each office. In a prestudy trial, the assay was found to be positive if an antibiotic dose had been taken within 16 hours of urine collection.

Patients were unaware of the study design. The treatment given followed the routine standard of care for acute otitis media in the community and as indicated in the literature. The only deviation from this was the request for a urine sample for assay at the one-week follow-up. The urine assay was performed at no charge to the patient, and any patient hesitation or refusal to provide a specimen was honored. Confidentiality of the urine assay results was maintained.

The three study factors—different offices, written instructions, and familiarity of the prescribing physician—were compared with compliance and outcome measures by the Pearson and Mantel-Haenszel chi-square tests, with subsequent evaluation for confounding by ethnic, socioeconomic, and age distributions. The data were then analyzed for any correlations between compliance and outcome measurements.

Results

The characteristics of patients at each office are depicted in Table 1. The group labeled low socioeconomic status (low SES) was defined as all Medicaid and sliding-fee scale patients, and the group labeled average socioeconomic status (average SES) was composed of patients with insurance or those who paid directly. The physician making the diagnosis of acute otitis media recorded whether he or she was the patient's usual physician.

Statistically significant differences were defined as those obtaining a P value of .05 or less.

The study populations at each of the various offices differed significantly from one another in age, socioeconomic status, and ethnic grouping. Office A consisted of a predominantly low socioeconomic status group of which 45 percent were nonwhite. Offices B and C had approximately one half low-income patients, but office B was more racially mixed than was office C. Office D consisted of an older, primarily white population of higher socioeconomic status than the other

Characteristic	Office (%)				P Value
	A	B	C	D	
Positive history of acute otitis media	62	55	64	66	NS
Positive history of myringostomy tubes	10	6	0	8	NS
Aged under 3 years	78	80	83	58	.0031
Ethnic group					
White	55	60	82	97	
Hispanic	27	26	14	3	<.0001
Other	18	14	4	0	
Low socioeconomic status	78	44	50	10	<.0001
Written instructions given	50	49	45	49	NS
Saw own physician	34	57	48	51	NS
Total number of cases	104	69	27	90	

A—Government-subsidized residency teaching office
 B—Community-hospital-owned residency teaching office
 C—University of Utah Family Practice Center
 D—Private practice

offices. These factors were evaluated as potential confounders in subsequent analyses.

Study Factors vs Compliance

Sixty percent of patients returned for follow-up within 11 days. Compliance as measured by follow-up rates within 10 days was significantly better at the private practice office than at the other clinics (80 percent vs 51 percent, $P = .0002$). Similarly, if the patients saw their own physicians, they were more likely to return for follow-up as requested (69 percent vs 50 percent, $P = .04$). Written instructions had no effect on this follow-up rate.

Compliance as measured by positive urine assays was 82 percent. Overall, the variation in this compliance between offices was not significant. If one compares the private practice with the government-subsidized clinic, however, a statistically significant difference was found, with the private prac-

tice having greater compliance (90 percent vs 72 percent, $P = .04$). The percentage of positive urine assays was affected by the written instructions and the family's familiarity with the prescribing physician and confounded by socioeconomic status. Written instructions were associated with a decrease in positive urine assays, primarily in the low socioeconomic groups. Ninety-two percent of those without written instructions had a positive urine assay compared with 74 percent of those with written instructions ($P = .02$). Familiarity with the prescribing physician, however, did correlate with better compliance, although this was observed only in the lower socioeconomic category (85 percent vs 33 percent, $P = .02$).

Study Factors vs Outcome

Eighty-three percent of patients who returned for follow-up had normal middle ears on examina-

tion by 26 days. Of those who did come back, 92 percent continued follow-up visits until they had a diagnosis of normal or improved examination. Furthermore, 19 percent of patients had clinically diagnosed recurrence within the five-month study period.

None of the study factors (different offices, written instructions, or familiarity of the prescribing physician) was found to be associated with the number of recurrences or days until the ears were found to be clear. However, those given written instructions were more likely to continue to return for follow-up until a diagnosis of normal or improved was given than those without the instructions (odds ratio [OR] = 4.46, $P = .03$). Patients who had seen their own physician at the initial visit for acute otitis media were more likely to have a diagnosis of "not improved" at the last follow-up visit they attended (OR = 4.0, $P = .03$).

Compliance vs Outcome

Each compliance measurement was analyzed for associations with outcome measurements via the Pearson chi-square test. None was significant at the $P = .05$ level.

Discussion

The compliance rates in this study—60 percent follow-up within 11 days, and 82 percent positive urine assays at that follow-up visit—were similar to those reported in the literature. That urine assays were performed only on patients who had already demonstrated some compliance by keeping their follow-up appointment may have artificially elevated compliance rates as demonstrated by urine assay. Therefore, characteristics of those who failed to return in less than 11 days were evaluated. The Hispanic population and the low socioeconomic group were less likely to follow up as requested (OR = 2.2 and 2.7, $P = .03$ and $.0003$, respectively). If all patients who did not return had had a negative urine assay (obviously the worst

case, but not a valid assumption), associations previously observed remain.

"Office type" is a composite of numerous variables related to the demographic characteristics of the patients served, the numbers and specialties of providers, the location of the office, and so on. The differences found in compliance measures were most marked between the private practice office and the government-subsidized residency teaching office. In addition, greater differences in compliances were seen among different socioeconomic groups within the government-subsidized office than were seen among socioeconomic groups at the other offices. This finding supports the concept that low-income populations are by no means a homogeneous group. The differences seen here may be due to differences in locale (neighborhood standards, education, cultural differences) or to varied selection of offices by patients related to the patient's medical beliefs.

Surprisingly, the use of written instructions was not associated with improved compliance. In fact, the percentage of positive urine assays was lower in the low-income population when written instructions were given than when they were not. One reason for this might be that those given written instructions were more likely to continue for follow-up and thus were overrepresented in the assay group. However, follow-up at less than 11 days was not influenced by written instructions even when analyzed by socioeconomic status, age of patient, or ethnic group. Another possibility is that the group without written instructions was given better oral instructions, which improved compliance in that group. Comments from the physicians involved indicate that written instructions were usually not noticed until the end of the visit, after all instructions were given, thereby making this possibility less likely. These findings did not support the findings of Sharpe and Mikeal,⁸ in which written instructions dispensed by a pharmacy with an antibiotic improved compliance as measured by pill counts from 63 percent to 85 percent ($n = 80$). That study was done in a black, low-income population. Because of the marked differences in methodology and setting, specific reasons for this discrepancy remain unclear.

Overall, compliance was improved when patients saw their own physicians as opposed to an unfamiliar physician, primarily in the patients of low socioeconomic status. Although the private

practice office did not show the socioeconomic association with positive urine assays seen in other offices when the patients saw their own physicians, this may be due to the scarcity of low-income patients in that practice. This phenomenon may be explained by an attribute often found in the lower socioeconomic populations and described by Strauss.¹³ He found that low-income groups respond better to personal relationships than to professional "impersonality." Furthermore, their behavior is frequently more crisis oriented in nature. One might imagine that in a situation in which an unfamiliar physician advised a patient to return even if he or she feels well, this advice could be readily disregarded. This finding is in agreement with the studies by Charney et al⁴ and Green et al,⁷ in which compliance with a short course of antibiotics was improved when the patient saw his own physician. One cannot tell, without a controlled study, whether patients who comply also tend to arrange to see their own physician, or whether seeing their own physician, in turn, improves compliance.

The finding that those seeing their own physicians were more likely to have a diagnosis of not improved than those with otitis media diagnosed by another physician causes concern. As compliance was good in this group, one must question the value of treatment, the resistance of the infection, or the evaluative capabilities of the physician. Could it be that the physicians were more willing to address nonimprovement in their own patient—with the attendant responsibilities of changing treatment strategies and scheduling a return visit—than they were in unfamiliar patients? Evaluation of this phenomenon with a more objective measure of outcome, such as tympanometry, would help clarify this unexpected finding.

That the study factors, and in turn compliance, had little association with outcome was anticipated. In light of the numerous studies debating how to treat and even *whether* to treat acute otitis media, it is clear that the benefits of treatment and hence the benefits of compliance with that treatment are difficult to demonstrate. The serious complications of acute otitis media—meningitis, mastoiditis, bacteremia—occur rarely enough that a much larger study would be needed to demonstrate advantages of treatment.

Two components of the study design may have influenced the results. The patients were asked to

return to the office seven days after the initial diagnosis. This early follow-up may have had a positive influence on compliance. Also, evaluation of the middle ear was made on clinical grounds. Tympanometry would provide improved objectivity on outcome measurements.

This study illustrates that results from compliance studies may vary greatly, depending on the office or population served. Extrapolation from one group to all settings can lead to invalid assumptions. Furthermore, factors one feels "should" improve compliance may not actually do so, as shown by the use of written instructions. Each factor requires a controlled study to evaluate its efficacy.

Finally, in offices treating low-income populations, attempts to have patients see their own physicians may result in improved compliance. Further study is necessary to clarify whether such an intervention would alter compliance.

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