Does Patient Education Cause Side Effects?

A Controlled Trial

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Ninety-eight adults treated with erythromycin for a variety of illnesses were randomized to two groups: the informed group received patient education about drug side effects, and the uninformed group were given no such information. Overall, 10% of the uninformed and 8% of the informed group felt the erythromycin bothered them in some way. There were no significant differences in the occurrence of various individual side effects. Compliance with therapy and the results of treatment were the same for both groups. In this study, informing patients about side effects of therapy did not have any detectable adverse effects. **J Fam Pract 1990; 31:62-64.**

Patient education is now widely accepted to be an integral part of good medical practice.[1] An aspect of patient education concerns medications. Educating patients about medication is being increasingly emphasized. Patients are taught how and when to take their medicine, how the medicine works, and what side effects can occur. For a number of drugs, federal regulations now require that patient education in the form of patient package inserts be provided to the patient with the prescription. The American Medical Association has developed a series of patient education handouts to inform patients about their medications. In many hospitals, it is considered the obligation not only of the physician but also of the nurse to provide information about medications to all patients at the time of discharge.[2]

Educating patients has been shown to be beneficial, primarily by improving medication compliance.[3-6] The safety of patient education, however, has not been well studied. As with any medical activity, procedure, medication, or process, a potential for side effects exists. Even placebos have been shown to have side effects.[7]

The study reported here was designed to answer one aspect of whether patient education about medication causes side effects. Fries and Loftus,[8] in an often quoted article, stated that "explicit suggestion of possible adverse effects causes subjects to experience these effects." Myers et al[9] in 1987 reported on a large multicenter trial of aspirin and sulfinpyrazone for unstable angina. Before admission in this trial, one group of patients was given a consent form that said in part that "side effects are not anticipated beyond occasional gastrointestinal irritation and, rarely, skin rash." The consent form given to a second group of patients did not mention the possibility of gastrointestinal irritation. The first group subsequently had a 44% incidence of minor gastrointestinal side effects; the second had only a 16% incidence ($P < .001$).

Does patient education about drug side effects really do any harm, as Fries and Loftus[8] and Myers et al[9] suggest? The present study was designed to address this question in the family practice setting.

METHODS

Ninety-eight patients in a private family practice formed the study population. Between August 1987 and June 1988 all patients over 18 years of age treated with erythromycin for an acute illness were enrolled in the study. All patients were seen by a single physician. Patients with a history of allergy or intolerance to erythromycin were not included.

Patients were randomized to informed (study) and uninformed (control) groups. The informed patients were told by the physician: "Erythromycin is a very effective and safe antibiotic, but occasionally side effects can occur. The most frequent side effects are abdominal cramping and discomfort. Nausea, vomiting, loss of appetite, and diarrhea occur less often. Take your medication with

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TABLE 1. PATIENT CHARACTERISTICS

Characteristic	Uninformed	Informed
Number	48	50
Age (years)	34.6	34.5
Sex		
Male	20	24
Female	28	26
Weight (kg)	71.3	75
Erythromycin dose (mg/kg)	14.6	14.1
Prior use of erythromycin (%)	36	37
Received other treatment in addition to erythromycin (%)	58	70
Subjective improvement reported by patient after treatment (%)	79	79

meals as this will make side effects less likely." The statement given the informed patients was carefully designed to simulate what the average practicing physician might actually tell patients in the course of a normal office visit. Uninformed patients were given their medication and instructed to take it with meals, but were given no information about side effects. To prevent bias, patients were blinded regarding the study. This was felt to be reasonable, as treatment decisions were not affected by inclusion, and all patients were treated within generally accepted standards of care.

Erythromycin base in a dose of 250 mg four times a day was used for all patients. Other forms of erythromycin, such as the ethylsuccinate or stearate, were not used. The drug was obtained from one supplier and was identical for all patients. The medication was dispensed by the physician to the patient at the time of the office visit. Patients were not given prescriptions to take to their pharmacy, as it would not be possible to control what information the pharmacist might give the patient about side effects.

After completing the medication, all patients were contacted by the office nurse and questioned regarding their response to treatment, compliance, and any side effects.

TABLE 2. COMPLIANCE WITH THERAPY

Compliance Characteristics	Uninformed	Informed
Mean number erythromycin pills taken per day	3.7	3.8
Patients reporting that they missed at least one pill (%)	66	60
Mean number of pills taken (out of 40 pills)	33.1	36.9

The nurse did not know the identity of informed and uninformed patients. Ninety-three of the 98 patients were contacted within 5 days of completing treatment. The longest delay in reaching a patient was 3 weeks.

RESULTS

Data on 98 patients were obtained, 48 in the uninformed and 50 in the informed group. The characteristics of the patients are shown in Table 1. Analysis of variance and chi-square analysis showed that there were no significant differences between the groups as to age, sex, weight (and hence dose per kilogram), previous use of erythromycin, the pretreatment incidence of side effects, or the use of other medications. Patients in both groups had a variety of illnesses including bronchitis, sinusitis, streptococcal pharyngitis, and skin infections. Patients in both the informed and uninformed groups had a 79% improvement with treatment.

Compliance with therapy is detailed in Table 2 and was similar for both groups. Patients took an average of 3.7 pills per day. Sixty-one of 97 patients failed to take at least one of the 40 pills. Thirty-four of 98 patients stopped taking their pills before completing therapy.

The occurrence of side effects before and after treatment in both groups is detailed in Table 3 and was no different by chi-square analysis. Overall, 10% of the un-

TABLE 3. PRETREATMENT AND POST-TREATMENT SIDE EFFECTS (PERCENT)

	Uninformed		Informed	
	Pretreatment	Post-treatment	Pretreatment	Post-treatment
Side effects				
Nausea	15	14	20	22
Abdominal discomfort	11	16	12	24
Abdominal cramps	4	12	4	22
Vomiting	4	0	0	0
Loss of appetite	30	21	20	12
Diarrhea	11	19	4	18
Patients who said that erythromycin caused any side effects		10		8

NOTE: Chi-square analysis showed no significant differences between the uninformed and informed groups.

informed and 8% of the informed patients reported that they had experienced side effects from the erythromycin. No patients refused treatment after being informed about possible side effects.

DISCUSSION

The present study was designed to look for any potential adverse effects of patient education in the family practice setting. At the outset of this study it was hypothesized that patient education increases the rate of drug side effects. It was surprising and reassuring that no ill effects were detected. In this study, informing patients did not alter the effectiveness of therapy; patients in both study groups had a 79% response to therapy. It was found that there was no significant increase in side effects as a result of informing the patient. The percentage of patients who felt that erythromycin bothered them in some way was actually a bit higher in the uninformed group (although the difference did not reach statistical significance). Erythromycin did cause abdominal discomfort, cramps, and diarrhea in some patients, but no more often in the informed than the uninformed group.

One might suspect that telling patients about a drug's side effects would make the patient afraid of the medication and less likely to take it as prescribed. In this study, educating patients about the possible side effects of erythromycin did not make the patients less likely to take their medicine. This study did not address the question of whether compliance could be improved by education about when and how to take medication. It should not be inferred from the present study that compliance is unaffected by patient education.

There are several possible methodological problems with the present study. The sample size was relatively small, although the conclusions of the study were statistically significant. As with any study, a larger sample size might have yielded different results. The study should be repeated using drugs other than erythromycin before general conclusions are drawn regarding patient education and drug side effects. The data regarding compliance were based solely on the follow-up questionnaire and were not confirmed by other means such as blood levels or pill counts. The physician treating the patients in the study could not be blinded. While the verbal information given to patients was controlled, the nonverbal communication could not be controlled.

CONCLUSIONS

In this study of 98 patients treated with erythromycin in family practice, informing patients about six potential side effects of therapy did not have any detectable adverse effects. The patients who were informed about the medication had similar responses to therapy, similar compliance, and rates of side effects similar to those of patients who were not informed. There was no detectable risk to informing patients about medication side effects. The results of this study support the hypothesis that providing information about side effects does not make them more frequent.

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