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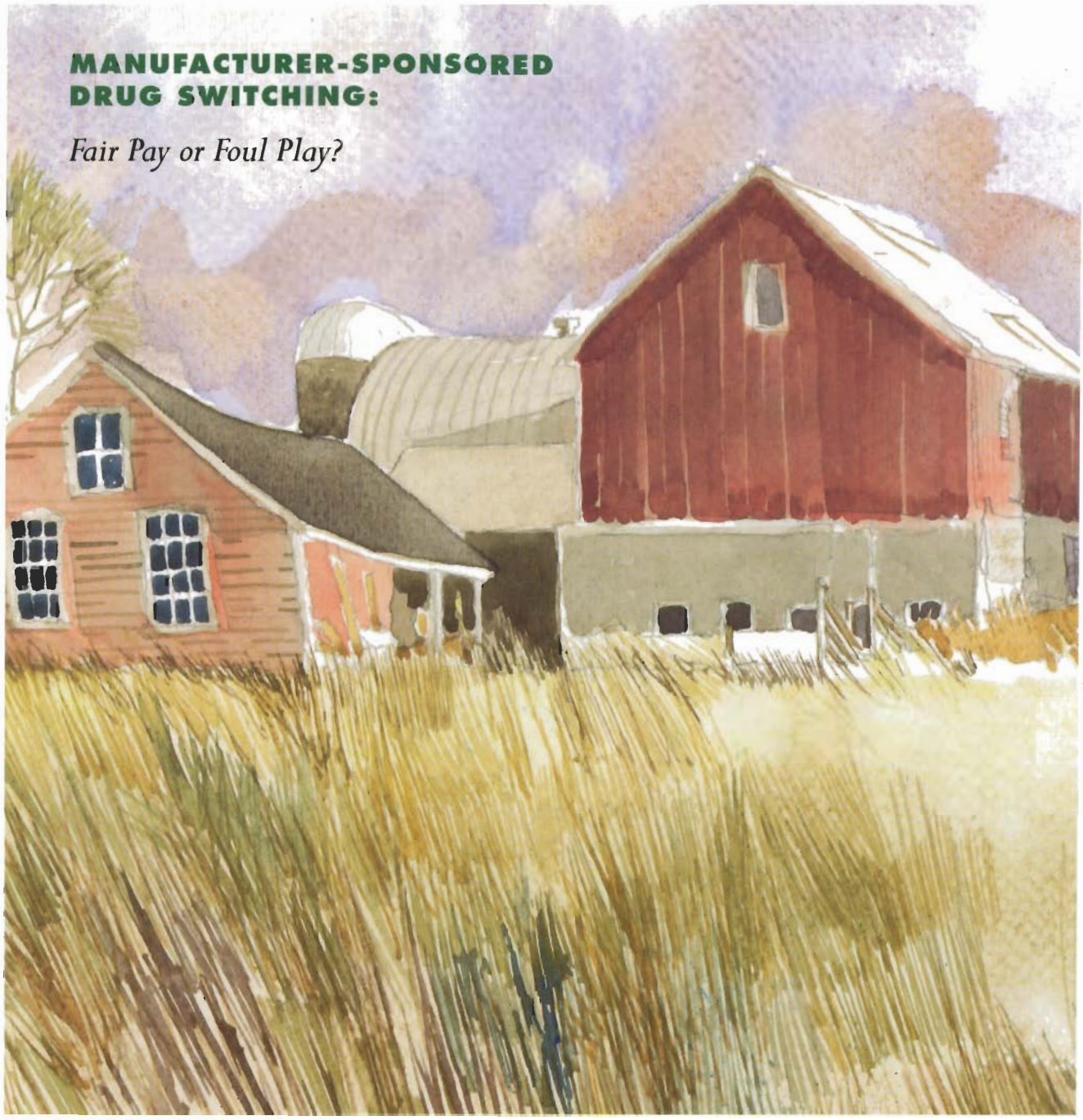
MANUFACTURER-SPONSORED DRUG SWITCHING:

Fair Pay or Foul Play?



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INITIATION OF BUSPIRONE FOR ANXIETY DISORDERS IN THE ELDERLY

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Objective: To provide guidelines for management of anxiety disorders using buspirone.
Setting: Long-term care facilities.
Practice Description: Consultant-only practice.
Practice Innovation: Buspirone is a preferred drug for treatment of anxiety disorders because it is not sedating and does not produce psychologic dependency.
Interventions: Residents of long-term care facilities were switched to buspirone from benzodiazepine drugs. After 30 days of therapy, gradual dose reduction and discontinuance was begun for benzodiazepines.
Main Outcome Measure: Individual case reports.
Results: After four months of interventions, most residents had been successfully switched to buspirone from benzodiazepine agents. Scores on anxiety rating scales were generally lower, and several problem patients were behaving and functioning much better.
Conclusion: Drug therapy outcome management programs, as exemplified by this approach to anxiolytic therapy, should be considered for implementation by consultant pharmacists.
Key Words: Anxiolytic agents; Anxiety disorders; Nursing homes; Adverse drug effects; Buspirone; Benzodiazepines; Anxiety rating scales; Outcomes.
Abbreviations Used: None.
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The proper identification and treatment of anxiety within long-term care facilities continue to challenge physicians, nursing staff, and consultant pharmacists. The difficulty results partly from the array of somatic symptoms that present and masquerade as different medical conditions. Anxiety is an emotional state characterized by undue nervousness and worry, generally because of an individual's concern over actual or potential danger. A simple admission to the nursing home can be enough to cause anxiety.

Anxiety is characterized in several ways. Since it also often occurs with other medical or psychiatric conditions, proper diagnosis is critical. In nursing home settings, anxiety affects the resident's life by:

1. Impairing social interactions;
2. Diminishing quality of life; and
3. Increasing the resident's concern with health status.

It also affects physicians and nursing staff by requiring more contact and interaction with the resident.

In this article, we review common pitfalls in the diagnosis of anxiety disorders and present an overview of proper pharmacotherapy with buspirone for these conditions. Two sample case studies are presented as illustrations of appropriate approaches and potential problems.

ANXIETY MISDIAGNOSED

Distinguishing between anxiety and depression is very difficult, since many patients have manifestations of each. Geriatric patients present an even bigger challenge to health care professionals. Fear of aging and dying may appear as dementia or confusion when the patient is really expressing consistent episodes of anxiety. Ongoing episodes of anxiety may result in chronic depression, which compound difficulties in determining underlying ideologies.

A common myth is that most older residents of nursing homes are demented. When present in long-term care staff, this prejudice causes caregivers to overlook the condition of

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anxiety. Acute episodes of mental trauma after loss of a lifelong mate, an irreversible illness, admission into a long-term care facility, terminal disease, loss of sight, hearing, speech, and persistent pain are just a few difficult problems that result in a treatable anxiety component.

Maladaptive Behavior as a Symptom of Anxiety

Patients may exhibit maladaptive behavior in response to these conditions. In the demented patient, anxiety may be expressed by continuous yelling, continuous calling for parents, insomnia, asking to go home, and hostile response to staff or caregivers. Ongoing drug therapy also must be considered as a possible cause of anxiety, including any of the following:

- Sedatives
- Antidepressants
- Antihistamines
- H_2 histamine antagonists
- B_2-adrenergic antagonists
- Antiparkinson drugs
- Neuroleptic agents with high anticholinergic side effects profiles
- Bronchodilators
- Stimulants

Since patients are often treated for maladaptive behavior with neuroleptic drugs, benzodiazepines, and antihistamines, the possibility of iatrogenic anxiety is very real. This approach to anxiety management often leads to more confusion, lethargy, and continuing falls and injuries.

Pharmacist-Conducted Physical Patient Assessments for Anxiety

During our facility reviews, we observe residents in the dining room during breakfast and lunch for symptoms of hangover, lethargy, and inability to remain awake while waiting to be served meals. For patients with these symptoms of overmedication, we conduct a comprehensive review of drug therapies and discuss the clinical situation with the nurse and the patient.

The nurse also has a list of other patients for the consultant pharmacist to see during the visit. This usually includes patients receiving meals in their rooms or other difficult patients who may be fearful of the staff, use the call light constantly, refuse treatments, or have other behavior problems. Usually these patients are already on numerous drug therapies to improve those problems, but without apparent success at resolving anxiety disorders.

We look closely at several categories of psychoactive drugs during these reviews. Antihistamine products such as diphenhydramine or hydroxyzine may cause problems through their anticholinergic side effects. They may cause patients to be unsteady on their feet, causing falls. Neuroleptic drugs such as phenothiazines will exacerbate some problems secondary to the anticholinergic side effects while placing the patient in a stupor. Short-acting benzodiazepines cause numerous side effects along with psychologic dependency.

Benzodiazepines are not the anxiolytics of choice in the elderly because of reduced metabolism in the liver. Drug therapy should reduce anxiety episodes while not sedating the older patient or producing unnecessary side effects.

Alternative Anxiolytic Therapy

We consider buspirone (Buspar) to be an acceptable and effective anxiolytic drug with a low side-effects profile. It does not sedate the geriatric patient or cause psychologic dependency. The total profile of this agent produced the outcome we wanted while reducing the need for benzodiazepine drugs. However, the drug does not produce an immediate response, so therapy must be initiated and maintained carefully to produce an acceptable clinical result.

We began an educational effort with the nurses and physicians to advise when to look for response and what to look for during buspirone therapy. Although some response to therapy is possible in about 10 days, positive patient outcomes are not fully observed until after 30 days. This situation may result in discontinuance of the drug therapy when

TABLE 1. SAMPLE CASE STUDIES

Patient 1

Eighty-four-year-old woman, diagnosis of Alzheimer's Disease, upon patient interview presented frightful distress, would not leave her room, and wanted to leave the facility and go back home. Zung Self-Rating Anxiety Index was 60 (marked-to-severe anxiety).

Medications

Lorazepam 1-mg tablet b.i.d. (8 a.m. and 4 p.m.)
Hydroxyzine 50-mg capsule b.i.d. (8 a.m. and 4 p.m.)
Diphenhydramine 50-mg capsule h.s. for sleep (8 p.m.)

Pharmacist Suggestions

- Start buspirone 10-mg tablet t.i.d.
- Taper to discontinuance lorazepam 1-mg tablet at 4 p.m. daily for 15 doses, then every other day at 4 p.m. for 15 doses then discontinue.
- Taper to discontinuance hydroxyzine 50-mg capsule at 8 a.m. daily for 15 doses, then every other day at 8 a.m. for 15 doses then discontinue.
- Taper to discontinuance diphenhydramine 50-mg capsule at 8 p.m. every other day for 15 doses, then discontinue.

Outcome

Patient currently on buspirone 10-mg tablet t.i.d. only. She goes to the dining room for all meals, does not resist care, seems to be satisfied with being in the nursing home. Zung score lowered to 45 (within normal range).

Patient 2

Eighty-two-year-old-man, diagnosis of agitation secondary to chronic obstructive pulmonary disorder, hostile to staff, constant concern about health, does not want to participate in any facility activities, overuse of call light. Zung Self-Rating Anxiety Index was 76 (most extreme anxiety).

Medications

Haloperidol 1-mg tablet b.i.d.
Benztropine mesylate 1-mg tablet b.i.d.
Flurazepam 15-mg capsule h.s.
Hydroxyzine 50-mg capsule every four hours as needed for extreme agitation.

Pharmacist suggestions

- Start buspirone 10-mg tablet t.i.d.
- Taper to discontinuance haloperidol 1-mg tablet at 8 p.m. daily for 15 doses, then every other day at 8 p.m. for 30 doses, then discontinue.
- Taper to discontinuance flurazepam 15-mg capsule at every other day at 8 p.m. for 30 doses, then discontinue.
- Taper to discontinuance benzotropine mesylate 1-mg tablet at 8 a.m. every other day for 15 doses, then discontinue.
- Discontinue hydroxyzine 50-mg capsule.

Outcome

Patient currently on buspirone 10-mg tablet t.i.d. only. He seems to have fewer problems with respiratory distress, will attend church meetings held in the facility, cooperates with staff in the delivery of care, has dramatically reduced the dependence on the call light. Zung's score decreased to 40 (within normal range).

nothing is observed after 10 days.

Another problem we encountered was the state Medicaid Program, which, before April 1, 1994, would pay for only one month of therapy without prior approval. However, if the anxiety diagnosis was supported through results from the Zung Self-Rating Anxiety Scale (adding the diagnosis of Generalized Anxiety Disorder), six months' therapy could be paid for by Medicaid. To obtain the necessary information for the pharmacy provider to submit a prior approval application, we had to educate nurse supervi sors on how to administer the test and get the information to the provider pharmacy. We also were trying to prove that through the buspirone drug therapy, the need for many other drugs would be reduced, along with other expensive patient care services. If this outcome could be achieved, the use of buspirone would save much more than it would cost.

Pharmacist-Initiated Buspirone Dosing Protocols

Our protocol was to suggest that buspirone 10-mg tablets be given at 8 a.m., 12 noon, and 8 p.m. daily for a period of 30 days before reduction of other medications was initiated. The purpose was to have the buspirone activity in place before reduction of other agents. In many cases we received the response "Why fix it if it isn't broken" from physicians. In fact, all the scores from the Zung Self-Rating Anxiety Scale test were in the 60s to 70s, indicating that many patients, although on current drug therapies, had marked to severe anxiety. This was an indication that it did indeed need fixing.

After 30 days of buspirone drug therapy, we initiated a gradual dose reduction of the benzodiazepines at about 25% every 30 days. Through this slow gradual dose reduction we hoped to remove the drug with the least resistance from the patient. We followed the same protocol on the reduction of antihistamines and neuroleptic drugs. Because of the slow onset of activity with buspirone, patients experiencing acute attacks of anxiety were placed on a long-acting benzodiazepine such as diazepam and buspirone. Use of a long-acting benzodiazepine provided immediate relief and allowed the buspirone the necessary time to respond. After control was achieved, the long-acting benzodiazepine was withdrawn and the patient maintained on the buspirone.

Evaluation of Anxiolytic Conversions

After four months of experience with the program, we assessed its success. Experiences with two patients are presented in Table 1, page 243.

We had been able to remove the benzodiazepine drugs, provide relief to the patient, and lower Zung scores. Patients who had refused to leave their rooms were going to the dining room for meals or to other activities. Problem patients who had been continually yelling or crying improved dramatically.

Other behavioral interventions such as placing patients in active areas of the facility helped to achieve better control and improve the quality of life for others. Excessive use of call lights by some patients was decreased, thereby reducing staff work chores. Removal of offending drug therapies reduced drug regimens, especially those aimed at treatment of vertigo, insomnia, maladaptive behavior, and tardive dyskinesia. All of these steps amounted to impressive savings in care costs through positive patient outcomes.

Conclusion

Developing drug therapy outcome management programs result in great savings in overall patient care costs. Formularies or other short-sighted approaches to cost containment do succeed in reducing expenses in certain cost centers, but usually elevate costs in other areas. Through the pharmacy clinician's approach to comprehensive drug therapy management, drug therapy costs may or may not increase, but the savings in the other expensive cost centers will dramatically decrease, thereby reducing total care costs. We believe that rational drug therapy management of anxiety through the use of buspirone is a proven cost-effective approach.