Ativan, Benadryl, and Haldol (ABH) Gel and Ativan, Benadryl, Haldol, and Metoclopramide (ABHM) Gel in the Treatment of Nausea

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In March and April of 2000, we provided palliative therapy for a 78-year-old woman who was dying of cancer of the stomach. The patient was suffering more from nausea than from pain. Her physician had prescribed antiemetic trimethobenzamide suppositories (Tigan) 200 mg to be used every 6 to 8 hours as needed, but this medication did not relieve the nausea.

As a pharmacist, I meet weekly with a hospice care interdisciplinary team for the purposes of assessing and determining treatments for terminally ill patients. At our meeting on March 15, 2000, I suggested that a topical Ativan, Benadryl, and Haldol (ABH) gel to which pentoxifylline had been added be prescribed to alleviate this patient’s nausea, and her physician agreed. ABH gel is a combination formula mixed in a Pluronic lecithin organogel in the following concentrations:
- Lorazepam (Ativan) 1 mg/mL
- Diphenhydramine (Benadryl) 25 mg/mL
- Haloperidol (Haldol) 1 mg/mL
- Pentoxifylline (Trental) 50 mg/mL (to enhance absorption)

The patient was instructed to apply 1 mL of this gel to her wrist every 4 to 6 hours as needed.

At the time of our interdisciplinary team meeting on March 29, 2000, the patient was still experiencing some nausea. I suggested adding metoclopramide (Reglan) in a 10-mg/mL concentration to the gel; the dose (a topical application of 1 mL every 4 to 6 hours) was to remain unchanged.

After 2 doses of treatment with this formulation, the patient’s nausea was relieved. She continued this protocol and experienced relief from nausea until her death in late April 2000.

We have found this combination of topically applied medication to be very effective in decreasing the anxiety and nausea produced by some diseases during the end-of-life process.

Suggested Reading

DermaZinc-Plus with Clobetasol for the Treatment of Psoriasis

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In late April 2000, a 32-year-old man became the patient of a physician located close to our pharmacy. In 1995, the patient had been diagnosed as having psoriasis, for which he had been treated by several physicians. When the patient received his diagnosis, his family history indicated that no other relatives had psoriasis, but the condition was subsequently diagnosed in his aunt and in his grandfather.

The psoriatic lesions first appeared on the patient’s elbow as a scaling sore that did not heal, and in 1997 the lesions appeared on his scalp. He had been treated with a number of agents, including betamethasone lotion 0.05% (Diprolene), calcipotriene topical solution 0.005% (Daivones), and calcipotriene and mometasone furoate cream (Forteo). The patient was still experiencing some active disease. He had been receiving phototherapy (PUVA) with minimal benefit.

In March 2000, I suggested to the pharmacist’s representative that DermaZinc-Plus with Clobetasol be used to treat the patient’s psoriasis. The pharmacist’s representative, who was also a dermatologist, prescribed this product. The patient was instructed to apply the gel twice daily. This treatment was effective in reducing the scaling and redness of the lesions.

Suggested Reading
through pain was related to the primary cancer, and the secondary cancer was the cause of that pain in 44 of the remaining 56 patients. The average number of daily pain episodes was five, and 50% of the subjects rated the pain as being severe or excruciating. In eight patients (66.6%), the pain lasted 30 minutes or less.

At the time of the study, all subjects had been receiving morphine in various protocols (listed in Table 2 of the article) as regular analgesia and were also using short-acting oral morphine (on average, twice daily) for breakthrough pain. Relief from breakthrough pain provided by morphine was rated as "good" by four patients (33%), "fair" by five (42%), and "poor" by three (25%).

A summary of the trial, each patient began a protocol of receiving 20 µg of intranasally administered fentanyl citrate (INFC) from a 10-ml nasal spray bottle with a 0.2-ml reservoir. Each spray bottle delivered a 0.2-ml bolus dose with each spray. This treatment with INFC was to replace treatment with short-acting oral morphine, which had been used as the rescue medication before the study. If the breakthrough pain was completely relieved by INFC, patients were to continue with the dosage. If partial relief or no pain relief resulted, each patient was given a second bottle to provide sufficient drug to spray both nostrils. All patients required two bottles of the preparation. Patients were asked to use the INFC spray for five consecutive occurrences of breakthrough pain. The degree of pain was assessed by means of a visual analogue scale (VAS) before treatment with INFC and 3, 5, 10, 15, and 20 minutes after administration of that medication. Nonbreakthrough analgesics that were taken before the trial were continued without change in the dose.

During the trial, patients were monitored for adverse events. At the conclusion of the trial, the subjects were asked whether they had experienced adverse events and how they rated the pain-managing efficacy of INFC. Each subject was also asked to list the advantages and disadvantages of taking medication to control pain.

After treatment with INFC, eight patients (66%) demonstrated a reduction in the VAS score. Four of those patients noted a reduction in pain 5 minutes after having used INFC, and seven patients noticed pain relief after 10 minutes. Those eight patients rated the efficacy of INFC as "good" or "very good." Nine patients (75%) indicated that INFC was as effective as or better than morphine, and four (33%) rated the effectiveness of INFC as "moderate" or "bad." According to the author, patients who had been receiving the lowest daily doses of morphine showed a decline in the VAS score after treatment with INFC, and those who had been receiving a daily morphine equivalent of 120 mg or more did not rate the efficacy of INFC in those symptoms disappeared as the drug was used repeatedly. No systemic adverse events as a result of treatment were noted. At the conclusion of the study, nine patients (75%) said that they would continue treatment with INFC, and the remaining subjects were dissatisfied with the effectiveness of the preparation rather than the system of delivery.

The author notes that before the study, the patients were experiencing an average of 4.2 cycles per day for breakthrough pain, which requires approximately 1 hour to achieve maximum concentration and produces analgesia for a duration of about 4 hours. Because breakthrough pain may occur several times per day for short periods, the effects of short-acting morphine used as a rescue medication may continue beyond the duration of pain; repeated dosing can result in adverse effects. Parenterally administered opioids used when rapid pain relief is required have many disadvantages for the patient: Their administration is invasive and uncomfortable. However, INFC may be provided in a rapidly acting, easily, and painlessly absorbed through the nasal mucosa and, because it has a less toxic effect on local tissue, it can be used as long-term therapy. It is delivered as a bolus dose to the site of absorption and becomes effective within 10 minutes of administration.

Legal Update

Compounding Law Rescinded

In 1997 Congress passed a compounding law as part of the Federal Food and Drug Administration Modernization Act of 1997 (FDAMA). A section of this compounding law relating to advertising was challenged for its constitutionality during the last three years.

On Tuesday, February 6, 2001, the 9th Circuit Court of Appeals ruled that the government’s restricting advertising is unconstitutional. The court ruled that additional studies be conducted to determine the role of that therapy in the management of cancer-related breakthrough pain.

In its opinion, the Court stated that the FDA failed to prove that they have a substantial interest in preventing widespread compounding. They stated that FDA fails to support the opinion that increased distribution of compounded drugs is dangerous because of the health risks associated with large numbers of patients taking such drugs. The decision states that most evidence runs to the contrary noting that compounding is legal under state law and that most states require pharmacists to know how to compound. In essence, the Court ruled to prove that compounding is unsafe and should be limited.

Pharmacists are licensed and regulated by state boards of pharmacy. Most states have laws specifically setting forth parameters for pharmacy practice. In addition, the National Association of Boards of Pharmacy has published model acts for states to adopt to regulate compounding practice and the United States Pharmacopeia has created an entire chapter on professional compounding practice for pharmacists to refer.

Although the implication of the court’s decision is unclear from regulatory standpoint, the practice of compounding as necessary was clearly upheld.