Assessing the osteopathic medical profession's progress

Three years ago, when a new format for the annual *JAOA* education issue was adopted, our goal was to provide a compendium of information on osteopathic medical education and a means to assess the profession's growth and development. As this current edition shows, important progress has been achieved in these 3 short years, as follows:

- There has been a dramatic increase in the number of approved and funded intern positions. As a result, graduating DOs are now assured of the availability of osteopathic internships and a wider choice of hospital location.
- Changes also have been made in the intern program curriculum to provide specialty tracks and more efficient utilization of the first postdoctoral training year for physicians preparing for residencies.
- More DOs are now in residency training in osteopathic institutions than ever before.
- Because of sweeping changes initiated and approved by the AOA Board of Trustees, DOs

who have completed or are enrolled in non-AOA-approved allopathic residency programs can now have that training approved.

The information offered in this annual education issue of the *JAOA* has been compiled by the AOA staff and the American Association of Colleges of Osteopathic Medicine. Updated statistics are presented on osteopathic medical students, osteopathic medical school finances, postdoctoral training, continuing education, and research.

Osteopathic medical education's progress during these past 3 years clearly shows that today's osteopathic medical student now enjoys a wider scope of educational and specialty choices than ever before. The future progress of the profession rests on this ever-expanding base of educational development and responsiveness to meet the changing healthcare needs of Americans.

SANDRA M. WILLIAMSON
Executive Editor

1 THINK FAST. THINK SELDANE.®

Maximum on-the-job relief
from the first dose through the season

SELDANE®

(terfenadine) 60 mg tablets BID
for seasonal allergic rhinitis

Starts fast and lasts

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Before prescribing Seldane, please see brief summary of prescribing information, which appears on the reverse side.

SELAC 950

6498PO

Seldane®

(terfenadine) 60 mg Tablets

BRIEF SUMMARY

CAUTION: Federal law prohibits dispensing without prescription.

DESCRIPTION

Seldane (terfenadine) is available as tablets for oral administration. Each tablet contains 60 mg terfenadine. Tablets also contain, as inactive ingredients: corn starch, gelatin, lactose, magnesium stearate, and sodium bicarbonate.

INDICATIONS AND USAGE

Seldane is indicated for the relief of symptoms associated with seasonal allergic rhinitis such as sneezing, rhinorrhea, pruritus, and lacrimation.

CONTRAINDICATIONS

Seldane is contraindicated in patients with a known hypersensitivity to terfenadine or any of its ingredients.

PRECAUTIONS

General: Terfenadine undergoes extensive metabolism in the liver. Patients with impaired hepatic function (alcoholic cirrhosis, hepatitis), or on ketoconazole or troleandomycin therapy, or having conditions leading to QT prolongation (e.g. hypokalemia, congenital QT syndrome) may experience QT prolongation and/or ventricular tachycardia at the recommended dose. The effect of terfenadine in patients who are receiving agents which alter the QT interval is not known. These events have also occurred in patients on macrolide antibiotics, including erythromycin, but causality is unclear. The events may be related to altered metabolism of the drug, to electrolyte imbalance, or both.

Information for patients: Patients taking Seldane should receive the following information and instructions. Antihistamines are prescribed to reduce allergic symptoms. Patients should be questioned about pregnancy or lactation before starting Seldane therapy, since the drug should be used in pregnancy or lactation only if the potential benefit justifies the potential risk to fetus or baby. Patients should be instructed to take Seldane only as needed and not to exceed the prescribed dose. Patients should also be instructed to store this medication in a tightly closed container in a cool, dry place, away from heat or direct sunlight, and away from children.

Drug Interactions: Preliminary evidence exists that concurrent ketoconazole or macrolide administration significantly alters the metabolism of terfenadine. Concurrent use of Seldane with ketoconazole or troleandomycin is not recommended. Concurrent use of other macrolides should be approached with caution.

Carcinogenesis, mutagenesis, impairment of fertility: Oral doses of terfenadine, corresponding to 63 times the recommended human daily dose, in mice for 18 months or in rats for 24 months, revealed no evidence of tumorigenicity. Microbial and micronucleus test assays with terfenadine have revealed no evidence of mutagenesis.

Reproduction and fertility studies in rats showed no effects on male or female fertility at oral doses of up to 21 times the human daily dose. At 63 times the human daily dose there was a small but significant reduction in implants and at 125 times the human daily dose reduced implants and increased post-implantation losses were observed, which were judged to be secondary to maternal toxicity.

Pregnancy Category C: There was no evidence of animal teratogenicity. Reproduction studies have been performed in rats at doses 63 times and 125 times the human daily dose and have revealed decreased pup weight gain and survival when terfenadine was administered throughout pregnancy and lactation. There are no adequate and well-controlled studies in pregnant women. Seldane should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic effects: Seldane is not recommended for nursing women. The drug has caused decreased pup weight gain and survival in rats given doses 63 times and 125 times the human daily dose throughout pregnancy and lactation. Effects on pups exposed to Seldane only during lactation are not known, and there are no adequate and well-controlled studies in women during lactation.

Pediatric use: Safety and effectiveness of Seldane in children below the age of 12 years have not been established.

ADVERSE REACTIONS

Experience from clinical studies, including both controlled and uncontrolled studies involving more than 2,400 patients who received Seldane, provides information on adverse experience incidence for periods of a few days up to six months. The usual dose in these studies was 60 mg twice daily, but in a small number of patients, the dose was as low as 20 mg twice a day, or as high as 600 mg daily.

In controlled clinical studies using the recommended dose of 60 mg b.i.d., the incidence of reported adverse effects in patients receiving Seldane was similar to that reported in patients receiving placebo. (See table below.)

ADVERSE EVENTS REPORTED IN CLINICAL TRIALS

Adverse Event	Percent of Patients Reporting			All Clinical Studies**	
	Seldane N=781	Placebo N=665	Control N=628**	Seldane N=2482	Placebo N=1478
Central Nervous System					
Drowsiness	9.0	8.1	10.1	8.5	8.2
Headache	6.3	7.4	3.8	15.8	11.2
Fatigue	2.9	0.9	5.8	4.5	3.0
Dizziness	1.4	1.1	1.0	1.5	1.2
Nervousness	0.9	0.2	0.6	1.7	1.0
Weakness	0.9	0.6	0.2	0.6	0.5
Appetite Increase	0.6	0.0	0.0	0.5	0.0
Gastrointestinal System					
Gastrointestinal Distress					
(Abdominal distress, Nausea, Vomiting, Change in Bowel habits)	4.6	3.0	2.7	7.6	5.4
Eye, Ear, Nose, and Throat					
Dry Mouth/Nose/Throat	2.3	1.8	3.5	4.8	3.1
Cough	0.9	0.2	0.5	2.5	1.7
Sore Throat	0.5	0.3	0.5	3.2	1.6
Epistaxis	0.0	0.8	0.2	0.7	0.4
Skin					
Eruption (including rash and urticaria) or itching	1.0	1.7	1.4	1.6	2.0

*Duration of treatment in "CONTROLLED STUDIES" was usually 7-14 DAYS.

**Duration of treatment in "ALL CLINICAL STUDIES" was up to 6 months.

***CONTROL DRUGS: Chlorpheniramine (291 patients), d-Chlorpheniramine (189 patients), Clemastine (146 patients)

Rare reports of severe cardiovascular adverse effects have been received which include arrhythmias (ventricular tachycardia, torsades de pointes, ventricular fibrillation), hypotension, palpitations, and syncope. In controlled clinical trials in otherwise normal patients with rhinitis, at doses of 60 mg b.i.d. small increases in QTc interval were observed. Changes of this magnitude in a normal population are of doubtful clinical significance. However, in another study (N=20 patients) at 300 mg b.i.d. a mean increase in QTc of 10% (range -4% to +30%) (mean increase of 48 msec) was observed without clinical signs or symptoms.

In addition to the more frequent side effects reported in clinical trials (See Table), adverse effects have been reported at a lower incidence in clinical trials and/or spontaneously during marketing of Seldane that warrant listing as possibly associated with drug administration. These include: alopecia (hair loss or thinning), anaphylaxis, angioedema, bronchospasm, confusion, depression, galactorrhea, insomnia, menstrual disorders (including dysmenorrhea), musculoskeletal symptoms, nightmares, paresthesia, photosensitivity, seizures, sinus tachycardia, sweating, tremor, urinary frequency, and visual disturbance.

In clinical trials, several instances of mild, or in one case, moderate transaminase elevations were seen in patients receiving Seldane. Mild elevations were also seen in placebo treated patients. Marketing experiences include isolated reports of jaundice, cholestatic hepatitis, and hepatitis. In most cases available information is incomplete.

OVERDOSAGE

Information concerning possible overdose and its treatment appears in Full Prescribing Information.

DOSE AND ADMINISTRATION

One tablet (60 mg) twice daily for adults and children 12 years and older.

Product Information as of July, 1990

MARION MERRELL DOW INC.
Prescription Products Division
Kansas City, MO 64114

5 months old. 2 packs a day.

This is David Jr. He's a smoker. But not by choice. You see, when David's parents smoke around him, he's smoking too.

And babies who breathe tobacco smoke are twice as likely to have chronic or recurring respiratory illnesses, according to both the 1986 U.S. Surgeon General's Report on Passive Smoking and a 1986 report issued by the National Research Council's Committee on Passive Smoking.

In America, 42% of all children under one year old live with at least one smoker. You can change that.

Warn your patients about the danger. And until you're able to help them quit, recommend that they don't smoke around their baby.

**TELL THEM NOT TO SMOKE.
THERE'S A BABY IN THE HOUSE.**