

Patient Questionnaires Offer Prognostic Data

BY MARY ELLEN SCHNEIDER

NEW YORK — The soft data that can be gathered from self-administered patient questionnaires are more telling about how a patient with rheumatoid arthritis is faring than are x-rays or some lab tests that are wrongly considered to be prognostic.

Dr. Theodore Pincus recently told a group of rheumatologists at a course

sponsored by New York University that “patient questionnaire scores are the most valuable data we collect in taking care of patients.”

“The rheumatologist should be leading the world in recognizing these matters, rather than trying to say that we can be like cardiologists and look at images,” said Dr. Pincus of the department of medicine at the university.

That’s why he encourages physicians

to make patient questionnaires a standard part of the assessment of RA patients and then document those numerical measurements for easy reference.

Questionnaires like the Routine Assessment of Patient Index Data 3 (RAPID3) can be administered cheaply—for just the cost of pencils and photocopies—and scored by physicians in 5-10 seconds, he said.

These types of patient-oriented mea-

asures are especially important in rheumatology where there is no single standard measure when it comes to diagnosis or predicting functionality, said Dr. Pincus.

Functional disability, patient global estimate, socioeconomic status, and age are better predictors of cost, work disability, and death in RA than are rheumatoid factor and radiographs, he noted.

Although the conventional measures that make up the American College of Rheumatology core data set have served the specialty well, they all have their limitations, said Dr. Pincus.

Joint counts are the most specific measure to assess patients with RA, but the measure is not necessarily the most significant when it comes to prognosis and management, he said. Joint counts may improve over time, even while joint damage and functional disability continue to progress.



Rheumatologists should be leading the way in recognizing the validity of patient-completed questionnaires.

DR. PINCUS

It also takes physicians significantly longer to perform a joint count than to score a patient self-assessment (about 1.5 minutes vs. about 5-10 seconds).

And many rheumatologists don’t actually perform formal tender and swollen joint counts on the patients they examine, he said.

Radiographs also have drawbacks, Dr. Pincus said. Although clinical trials have shown statistically significant data from radiographs, it’s still unclear how important they are clinically in individual patients, he said.

The usefulness of x-rays is also limited because treatment is often initiated prior to the emergence of erosions.

Laboratory tests, which are often seen by physicians and patients as the most important measures, also fall short in rheumatology. For example, medical textbooks have said for years that the erythrocyte sedimentation rate is increased in nearly all patients with active RA, but today the data show that many patients with active RA do not have an increased ESR, Dr. Pincus said.

Studies from around the world have shown that as many as 37%-45% of RA patients have an ESR value less than 28 mm/hour, which is within normal limits (J. Rheumatol. 1994;21:1227-37).

While a complete blood count test is often of great value, generally laboratory tests tend to be overrated in rheumatology, he said. ■

Disclosures: Dr. Pincus disclosed a financial relationship with a number of pharmaceutical companies including Amgen Inc., Bristol-Myers Squibb Co., Abbott Laboratories, Wyeth Pharmaceuticals, Genentech, and UCB.

Colcrys®

(colchicine, USP) tablets

COLCRYS® (colchicine, USP) tablets for oral use

Brief Summary of full Prescribing Information

The following is a brief summary only. Please see full Prescribing Information for complete product information.

INDICATIONS AND USAGE

COLCRYS® (colchicine, USP) tablets are indicated for prophylaxis and the treatment of gout flares.

Prophylaxis of Gout Flares: COLCRYS is indicated for prophylaxis of gout flares.

Treatment of Gout Flares: COLCRYS is indicated for treatment of acute gout flares when taken at the first sign of a flare.

Familial Mediterranean fever (FMF): COLCRYS is indicated in adults and children 4 years or older for treatment of familial Mediterranean fever (FMF).

CONTRAINDICATIONS

Patients with renal or hepatic impairment should not be given COLCRYS in conjunction with P-gp or strong CYP3A4 inhibitors. In these patients, life-threatening and fatal colchicine toxicity has been reported with colchicine taken in therapeutic doses.

WARNINGS AND PRECAUTIONS

Fatal Overdose: Fatal overdoses, both accidental and intentional, have been reported in adults and children who have ingested colchicine. COLCRYS should be kept out of the reach of children.

Blood Dyscrasias: Myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, pancytopenia, and aplastic anemia have been reported with colchicine used in therapeutic doses.

Drug Interactions: Colchicine is a P-gp and CYP3A4 substrate. Life-threatening and fatal drug interactions have been reported in patients treated with colchicine given with P-gp and strong CYP3A4 inhibitors. If treatment with a P-gp or strong CYP3A4 inhibitor is required in patients with normal renal and hepatic function, the patient’s dose of colchicine may need to be reduced or interrupted [see *DRUG INTERACTIONS*]. Use of COLCRYS in conjunction with P-gp or strong CYP3A4 inhibitors is contraindicated in patients with renal or hepatic impairment [see *CONTRAINDICATIONS*].

Monitor for toxicity and if present consider temporary interruption or discontinuation of COLCRYS.

Neuromuscular Toxicity: Colchicine-induced neuromuscular toxicity and rhabdomyolysis have been reported with chronic treatment in therapeutic doses. Patients with renal dysfunction and elderly patients, even those with normal renal and hepatic function, are at increased risk. Concomitant use of atorvastatin, simvastatin, pravastatin, fluvastatin, gemfibrozil, fenofibrate, fenofibric acid, or bezafibrate (themselves associated with myotoxicity) or cyclosporine with COLCRYS may potentiate the development of myopathy [see *DRUG INTERACTIONS*]. Once colchicine is stopped, the symptoms generally resolve within 1 week to several months.

ADVERSE REACTIONS

Prophylaxis of Gout Flares: The most commonly reported adverse reaction in clinical trials of colchicine for the prophylaxis of gout was diarrhea.

Treatment of Gout Flares: The most common adverse reactions reported in the clinical trial with COLCRYS for treatment of gout flares were diarrhea (23%) and pharyngolaryngeal pain (3%).

FMF: Gastrointestinal tract adverse effects are the most frequent side effects in patients initiating COLCRYS, usually presenting within 24 hours, and occurring in up to 20% of patients given therapeutic doses. Typical symptoms include cramping, nausea, diarrhea, abdominal pain, and vomiting. These events should be viewed as dose-limiting if severe as they can herald the onset of more significant toxicity.

DRUG INTERACTIONS

COLCRYS is a substrate of the efflux transporter P-glycoprotein (P-gp). Of the cytochrome P450 enzymes tested, CYP3A4 was mainly involved in the metabolism of colchicine. If COLCRYS is administered with drugs that inhibit P-gp, most of which also inhibit CYP3A4, increased concentrations of colchicine are likely. Fatal drug interactions have been reported. Physicians should ensure that patients are suitable candidates for treatment with COLCRYS and remain alert for signs and symptoms of toxicities related to increased colchicine exposure as a result of a drug interaction. Signs and symptoms of COLCRYS toxicity should be evaluated promptly and, if toxicity is suspected, COLCRYS should be discontinued immediately. See full Prescribing Information for a complete list of reported potential interactions.

USE IN SPECIFIC POPULATIONS

- In the presence of mild to moderate renal or hepatic impairment, adjustment of dosing is not required for treatment of gout flare, prophylaxis of gout flare, and FMF but patients should be monitored closely.
- In patients with severe renal impairment for prophylaxis of gout flares the starting dose should be 0.3 mg/day, for gout flares no dose adjustment is required but a treatment course should be repeated no more than once every 2 weeks. In FMF patients, start with 0.3 mg/day and any increase in dose should be done with close monitoring.
- In patients with severe hepatic impairment, a dose reduction may be needed in prophylaxis of gout flares and FMF patients; while a dose reduction may not be needed in gout flares, a treatment course should be repeated no more than once every 2 weeks.
- For patients undergoing dialysis, the total recommended dose for prophylaxis of gout flares should be 0.3 mg given twice a week with close monitoring. For treatment of gout flares, the total recommended dose should be reduced to 0.6 mg (1 tablet) x 1 dose and the treatment course should not be repeated more than once every two weeks. For FMF patients the starting dose should be 0.3 mg per day and dosing can be increased with close monitoring.
- Pregnancy: Use only if the potential benefit justifies the potential risk to the fetus.
- Nursing Mothers: Caution should be exercised when administered to a nursing woman.
- Geriatric Use: The recommended dose of colchicine should be based on renal function.

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