

β-Blocker Quality Measure Focuses on Outpatients

BY ALICIA AULT

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WASHINGTON — The National Committee for Quality Assurance will begin reporting in earnest next year on how many myocardial infarction patients are receiving β-blockers 6 months after hospital discharge, as recommended by the American Heart Association and the American College of Cardiology.

This follows the organization's an-

nouncement last month that it would no longer collect data on how many acute MI patients receive β-blockers within a week of hospital discharge.

First collected in 1996, that measure—an element of the Healthcare Effectiveness Data and Information Set (HEDIS)—was “retired” in May because so many patients are now meeting the benchmark, said NCQA president Margaret O’Kane at a briefing.

Ninety-eight percent of privately in-

sured patients older than 35 years who had survived a heart attack were prescribed a β-blocker upon discharge in 2006, according to the most recent NCQA State of Health Care Quality report.

Postdischarge β-blockers were prescribed to 94% of Medicare managed care patients and 88% of Medicaid managed care patients in 2006.

When the measure was first reported, only “two-thirds of U.S. patients who survived acute myocardial infarction received

β-blockers; today, nearly all do,” according to Dr. Thomas H. Lee, cochair of the NCQA Committee on Performance Measurement. “At least when it comes to this intervention, the U.S. health care system has become reliable” he said (N. Engl. J. Med. 2007;357:1175-7).

Thus, NCQA decided it would no longer collect this information. The organization decided to “evolve” the β-blocker measure by setting the bar higher, and began asking for the data in 2005, said Ms. O’Kane in an interview.

In the latest report, only 68% of Medicaid patients, 70% of Medicare patients, and 72% of privately insured patients were still taking β-blockers 6 months after an MI. There’s also a huge amount of variability among plans. Ms. O’Kane said she believes that putting more scrutiny on the 6-month measure is appropriate and will improve results.

Dr. James Dove, president of the American College of Cardiology, agreed that the 6-month measure was important—probably more important than whether patients were receiving β-blockers immediately after discharge.

Most post-MI care is done on an outpatient basis, said Dr. Dove, in an interview. Plus, “the data suggest that most people who are on a β-blocker at 6 months got it at discharge,” he said, adding that the new measure will capture both the immediate postdischarge data and the picture at 6 months. Dr. Dove practices at Prairie Cardiovascular Consultants in Springfield, Ill.

It will be a challenge to both health plans and physicians to improve compliance rates, he said. Electronic health records could help; health plans could use the systems to send reminders, for instance, said Dr. Dove.

Patient compliance, however, is one of the biggest hurdles. Patients might not take medications for a variety of reasons—cost, forgetfulness, fears about side effects, or because they feel better, he said.

“It’s our obligation as we see the patient to reinforce why they need to take the medication,” said Dr. Dove. ■

A clinical study using enoxaparin in pregnant women with mechanical prosthetic heart valves has been conducted [see *Warnings and Precautions* (5.7)].

• *Animal Data* - Teratology studies have been conducted in pregnant rats and rabbits at SC doses of enoxaparin up to 30 mg/kg/day or 211 mg/m²/day and 410 mg/m²/day, respectively. There was no evidence of teratogenic effects or fetotoxicity due to enoxaparin. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Lovenox is administered to nursing women.

Pediatric Use

Safety and effectiveness of Lovenox in pediatric patients have not been established.

Geriatric Use

Prevention of DVT in hip, knee and abdominal surgery; treatment of DVT. Prevention of ischemic complications of unstable angina and non-Q-Wave myocardial infarction

Over 2800 patients, 65 years and older, have received Lovenox in pivotal clinical trials. The efficacy of Lovenox in the geriatric (≥65 years) was similar to that seen in younger patients (<65 years). The incidence of bleeding complications was similar between geriatric and younger patients when 30 mg every 12 hours or 40 mg once a day doses of Lovenox were employed. The incidence of bleeding complications was higher in geriatric patients as compared to younger patients when Lovenox was administered at doses of 1.5 mg/kg once a day or 1 mg/kg every 12 hours. The risk of Lovenox-associated bleeding increased with age. Serious adverse events increased with age for patients receiving Lovenox. Other clinical experience (including postmarketing surveillance and literature reports) has not revealed additional differences in the safety of Lovenox between geriatric and younger patients. Careful attention to dosing intervals and concomitant medications (especially antiplatelet medications) is advised. Lovenox should be used with care in geriatric patients who may show delayed elimination of enoxaparin. Monitoring of geriatric patients with low body weight (<45 kg) and those predisposed to decreased renal function should be considered [see *Warnings and Precautions* (5.9) and *Clinical Pharmacology* (12.3)].

Treatment of acute ST-segment Elevation Myocardial Infarction (STEMI)

In the clinical study for treatment of acute STEMI, there was no evidence of difference in efficacy between patients ≥75 years of age (n = 1241) and patients less than 75 years of age (n=9015). Patients ≥75 years of age did not receive a 30 mg IV bolus prior to the normal dosage regimen and had their SC dose adjusted to 0.75 mg/kg every 12 hours [see *Dosage and Administration* (2.3)]. The incidence of bleeding complications was higher in patients ≥65 years of age as compared to younger patients (<65 years).

Patients with Mechanical Prosthetic Heart Valves

The use of Lovenox has not been adequately studied for thromboprophylaxis in patients with mechanical prosthetic heart valves and has not been adequately studied for long-term use in this patient population. Isolated cases of prosthetic heart valve thrombosis have been reported in patients with mechanical prosthetic heart valves who have received enoxaparin for thromboprophylaxis. Some of these cases were pregnant women in whom thrombosis led to maternal and fetal deaths. Insufficient data, the underlying disease and the possibility of inadequate anticoagulation complicate the evaluation of these cases. Pregnant women with mechanical prosthetic heart valves may be at higher risk for thromboembolism [see *Warnings and Precautions* (5.7)].

Renal Impairment

In patients with renal impairment, there is an increase in exposure of enoxaparin sodium. All such patients should be observed carefully for signs and symptoms of bleeding. Because exposure of enoxaparin sodium is significantly increased in patients with severe renal impairment (creatinine clearance <30 mL/min), a dosage adjustment is recommended for therapeutic and prophylactic dosage ranges. No dosage adjustment is recommended in patients with moderate (creatinine clearance 30-50 mL/min) and mild (creatinine clearance 50-80 mL/min) renal impairment [see *Dosage and Administration* (2.2) and *Clinical Pharmacology* (12.3)].

LOVENOX®

(enoxaparin sodium injection)

Hepatic Impairment

The impact of hepatic impairment on enoxaparin’s exposure and antithrombotic effect has not been investigated. Caution should be exercised when administering enoxaparin to patients with hepatic impairment.

Low-Weight Patients

An increase in exposure of enoxaparin sodium with prophylactic dosages (non-weight adjusted) has been observed in low-weight women (<45 kg) and low-weight men (<57 kg). All such patients should be observed carefully for signs and symptoms of bleeding [see *Clinical Pharmacology* (12.3)].

OVERDOSAGE

Accidental overdosage following administration of Lovenox may lead to hemorrhagic complications. Injected Lovenox may be largely neutralized by the slow IV injection of protamine sulfate (1% solution). The dose of protamine sulfate should be equal to the dose of Lovenox injected: 1 mg protamine sulfate should be administered to neutralize 1 mg Lovenox, if enoxaparin sodium was administered in the previous 8 hours. An infusion of 0.5 mg protamine per 1 mg of enoxaparin sodium may be administered if enoxaparin sodium was administered greater than 8 hours previous to the protamine administration, or if it has been determined that a second dose of protamine is required. The second infusion of 0.5 mg protamine sulfate per 1 mg of Lovenox may be administered if the aPTT measured 2 to 4 hours after the first infusion remains prolonged.

If at least 12 hours have elapsed since the last enoxaparin sodium injection, protamine administration may not be required; however, even with higher doses of protamine, the aPTT may remain more prolonged than following administration of heparin. In all cases, the anti-Factor Xa activity is never completely neutralized (maximum about 60%). Particular care should be taken to avoid overdosage with protamine sulfate. Administration of protamine sulfate can cause severe hypotensive and anaphylactoid reactions. Because fatal reactions, often resembling anaphylaxis, have been reported with protamine sulfate, it should be given only when resuscitation techniques and treatment of anaphylactic shock are readily available. For additional information consult the labeling of protamine sulfate injection products.

CLINICAL PHARMACOLOGY

Mechanism of Action

Enoxaparin is a low molecular weight heparin which has antithrombotic properties.

PATIENT COUNSELING INFORMATION

Patients should be told that it may take them longer than usual to stop bleeding, that they may bruise and/or bleed more easily when they are treated with Lovenox, and that they should report any unusual bleeding or bruising to their physician [see *Warnings and Precautions* (5.1, 5.5)].

Patients should inform physicians and dentists that they are taking Lovenox and/or any other product known to affect bleeding before any surgery is scheduled and before any new drug is taken [see *Warnings and Precautions* (5.3)].

Patients should inform their physicians and dentists of all medications they are taking, including those obtained without a prescription [see *Drug Interactions* (7)].

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