Real-Time Performance Data Improved VTE Prophylaxis

BY PATRICE WENDLING

CHICAGO — Real-time relay of the venous thromboembolism prophylaxis order status of all patients at a 550-bed tertiary care teaching hospital increased prophylaxis usage in the ICU and in medical and surgical units.

For at least 5 months after the intervention, 15 nursing units averaged a greater than 90% prevalence of venous thromboembolism (VTE) prophylaxis, a level reached by just 5 units prior to the intervention, Dr. Jason Stein and his colleagues at Emory University, Atlanta, reported in a poster at the annual meeting of the Society of Hospital Medicine.

Pulmonary embolism resulting from VTE is the leading preventable cause of hospital death. Yet a large U.S. registry study showed that most hospitalized patients with risk factors for deep-vein thrombosis did not receive prophylaxis (Am. J. Cardiol. 2004;93:259-62).

In the current study, pharmacologic VTE prophylaxis in the surgical ICU significantly increased from 78% at baseline to 94% after the intervention. That occurred without a significant rise in lone mechanical prophylaxis, which increased from 17.3% to 19.6%.

In a medical nursing unit, the intervention led to a significant increase in overall VTE prophylaxis (from 85% to 91%) that was almost entirely attributable to an increase in lone mechanical prophylaxis (from 14.6% to 20.2%).

Frontline processes, such as rounding format or timing of capture of new orders, may modulate the effect of the program, and thus explain the different outcomes between the two units, Dr. Stein and his colleagues said.

In the surgical ICU, simultaneous physical rounding on every patient is conducted every morning by all members of the frontline clinical team, including the responsible physician. A clinical pharmacist views the real-time relay-and-display program prior to rounds to call attention to appropriateness of VTE prophylaxis during rounds. New VTE prophylaxis orders are discussed and captured via new physician orders during rounds.

In contrast, the rounding format in the medical unit is asynchronous physical rounding on patients by clinical team members. A multidisciplinary team meets on weekday mornings to discuss patients. The charge nurse views the relay-and-display program to call attention to patients, with no order for VTE prophylaxis during the team meeting. New orders are discussed but not captured during the meeting, and the nurse follows up ad hoc.

"More research is needed to examine sustainability and to clarify features of the most effective implementations of relay-and-display strategies in hospitals," they said.

Dr. Stein disclosed stock holdings with Ingenious Med Inc. as well as honoraria from Sanofi. ■

FDA Requests More Data On Oral Anticoagulant

BY ELIZABETH MECHCATIE

The approval of the oral anticoagulant rivaroxaban is on hold while the manufacturer evaluates a "complete response" letter issued by the Food and Drug Administration, according to the manufacturer, Ortho-McNeil.

The FDA has requested more information about rivaroxaban, which is under review for the prevention of venous thromboembolism in patients undergoing hip or knee replacement surgery. A statement issued by the company said that Ortho-McNeil was evaluating the FDA's letter, and would address the questions raised as soon as possible. The FDA has not requested that any new clinical or nonclinical studies of safety and efficacy, according to the statement, which did not provide further details.

If approved, rivaroxaban, a direct Factor Xa inhibitor, would be the first oral anticoagulant approved for the two indications under review, and the first approved since warfarin. The FDA does not comment on products that are under review for approval.

The agency issues a complete response letter to a company when the review of a product approval application has been completed and the product cannot be approved based on available information. This has replaced the "approvable" and "nonapprovable" letters that the FDA previously issued.

In March, the majority of the FDA's Cardiovascular and Renal Drugs Advisory Committee agreed that data from four clinical trials showed that the anticoagulant had a favorable risk-benefit profile for the proposed indications. Panel members were concerned about off-label use of the drug, and about the possibility that it might be used for longer periods than the duration studied in hip replacement patients (35 days) and knee replacement patients (14 days). Although the majority agreed that the potential hepatotoxicity of the drug should not preclude approval, the panel agreed that long-term data on the hepatotoxicity risk were needed (HOSPITALIST NEWS, April 2009, p. 1).

Ortho-McNeil is a division of Johnson & Johnson Pharmaceutical Research & Development LLC. ■

New 80-Lead ECG System Can Improve Diagnostic Yield

BY BRUCE JANCIN

NEW ORLEANS — An 80-lead electrocardiographic body-surface mapping system improved detection of acute MI and unstable angina in the emergency department, compared with standard 12-lead electrocardiography.

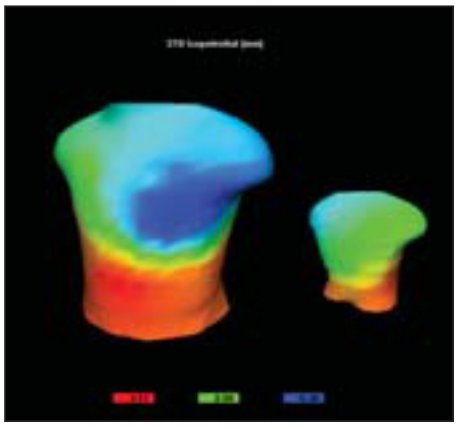
Use of the 80-lead technology—branded as PRIME ECG—in ED patients with chest pain and an abnormal but nondiagnostic 12-lead ECG should lead to markedly better risk stratification and earlier implementation of appropriate therapy, Dr. James W. Hoekstra said at the annual meeting of the Society for Academic Emergency Medicine.

Access to 80-lead ECG data could improve the diagnosis of occult STEMI and lead to better outcomes.

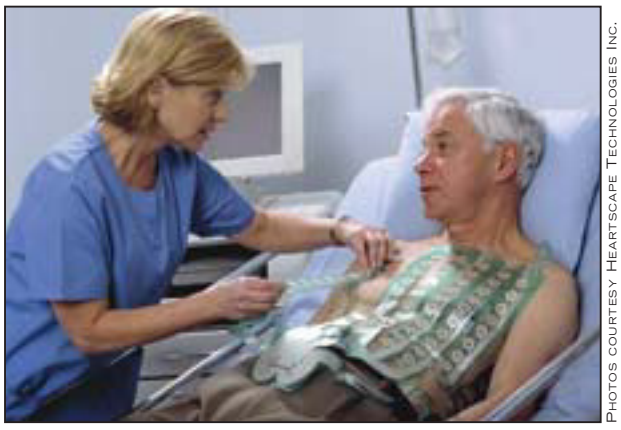
DR. HOEKSTRA

The 80-lead system includes a single-use disposable vest with 64 embedded anterior and 16 posterior chest leads, along with a computer that displays integrated three-dimensional color maps. The system also can display each lead individually. The rationale for the FDA-approved 80-lead technology is that the standard 12-lead ECG has major blind spots, most notably in detecting MIs that are posterior, inferior, right-sided, or high lateral, said Dr. Hoekstra, professor and chairman of the emergency medicine department at Wake Forest University, Winston-Salem, N.C.

The OCCULT MI (Optimal Cardiovascular Diagnostic Evaluation Enabling Faster Treatment of Myocardial Infarction) trial was an observational study of 1,830 patients presenting to a dozen major U.S. EDs with chest pain and a history highly suggestive of an ischemic cardiovascular event. Patients initially received a standard 12-lead ECG. If it showed evidence of an ST-elevation MI, patients were sent to the cardiac catheterization laboratory. If it was nondiagnostic, patients received the 80-lead PRIME ECG. Because the study was observational, physicians remained blinded to the 80-lead ECG findings.



The mapping system creates full-color images of the heart's electrical activity.



The disposable electrode vest of clear plastic strips is designed for rapid application and diagnosis.

PHOTOS COURTESY HEARTSCAPE TECHNOLOGIES INC.

The 12-lead ECG detected STEMI in 88 patients, while the 80-lead ECG increased that yield by 27.5%. But because physicians were unaware of the 80-lead ECG findings, STEMI patients detected by the new system were subjected to a conservative and delayed catheterization strategy. About half did not get to the catheterization lab until the next day. As a result, 30-day mortality in STEMI patients detected by 12-lead ECG was 8.0%, compared with 12.5% in those identified by 80-lead ECG.

The study implication is that if physicians had access to the 80-lead ECG findings—as in real-world clinical practice—the patients with occult STEMI would have been diagnosed and revascularized more expeditiously, with correspondingly better outcomes, according to Dr. Hoekstra.

OCCULT MI included 202 patients with unstable angina and 206 with non–ST-elevation MI. The sensitivity of 12-lead ECG for detection of NSTEMI was 10.7%, compared with 19.4% for the 80-lead ECG. The 80-lead system identified an additional 18 NSTEMI patients not detected by 12-lead ECG.

The 12-lead ECG had 7.1% sensitivity for detection of unstable angina, compared with 12.3% for the 80-lead system. That represented a 73% improvement over the 12-lead ECG. The 80-lead system identified an additional 21 unstable angina patients.

Specificity for acute coronary syndrome was high with both types of ECG. For example, the 12-lead ECG had 96.4% specificity for NSTEMI, compared with 93.9% for the 80-lead ECG. "That's a statistically significant difference, but I'm not sure that it's clinically significant," Dr. Hoekstra commented.

Dr. Hoekstra disclosed that he serves as a consultant to Heartscape Technologies Inc., which funded OCCULT MI and markets the PRIME ECG. ■

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