Low Molecular Weight Heparins: Drug Safety Communication - Recommendations to Decrease Risk of Spinal Column Bleeding and Paralysis

[Posted 11/06/2013]

FDA建議，當病人服用抗凝血藥品(如enoxaparin)時，醫療人員須考慮spinal catheter之放置、取出時機；spinal catheter移除後延遲使用抗凝血藥品，以降低spinal column bleeding的風險；脊椎穿刺(含epidural procedures和腰椎穿刺)後，延遲使用抗凝血藥品，以降低癱瘓的風險。這些建議(降低硬腦膜外及脊椎血腫)將加到抗凝血藥的仿單，如低分子量肝素、Lovenox及enoxaparin的學名藥。

建議

執行脊椎/硬腦膜外麻醉或脊椎穿刺前先核對preprocedure checklist，確定病人是否接受抗凝血劑，並確認導管置放或移除時，使用enoxaparin的適當時機。為了減少出血的潛在風險，應考慮抗凝血的劑量和半衰期：

- 以enoxaparin為例，給予預防深層靜脈栓塞劑量後，spinal catheter之放置、取出時機應延遲至少12小時。若病人使用更高劑量的enoxaparin (1 mg/kg每天兩次，或1.5 mg/kg每天一次)，則須延遲更長的時間(24小時)。
- Enoxaparin在Spinal catheter移除後的四小時內，不建議投予。
- 在所有情形下，應評估血栓形成的風險、手術的出血風險，和病人本身的危險因子。

[Posted 11/06/2013]

AUDIENCE: Pharmacy, Cardiology, Anesthesiology

ISSUE: The U.S. Food and Drug Administration (FDA) is recommending that health care professionals carefully consider the timing of spinal catheter placement and removal in patients taking anticoagulant drugs, such as enoxaparin, and delay dosing of anticoagulant medications for some time interval after catheter removal to decrease the risk of spinal column bleeding and subsequent paralysis after spinal injections, including epidural procedures and lumbar punctures. These new timing recommendations, which can decrease the risk of epidural or spinal hematoma, will be added to the labels of anticoagulant drugs known as low molecular weight heparins, including Lovenox and generic enoxaparin products and similar products.

BACKGROUND: Epidural or spinal hematomas are a known risk of enoxaparin in the setting of spinal procedures and are already described in the Boxed Warning and the Warnings and Precautions sections of the labels for Lovenox and generic enoxaparin products. However, these serious adverse events continue to occur (see Data Summary). To address this safety concern, FDA worked with the manufacturer of Lovenox, Sanofi-Aventis, to further evaluate this risk and to update the Warnings and Precautions section of the Lovenox label with these additional timing recommendations. The labels for generic enoxaparin products will also be revised accordingly, as will those of other low molecular weight heparin-type products.

It is important to note that all anticoagulants carry the risk of causing spinal bleeding when used in conjunction with epidural/spinal anesthesia or spinal puncture. We are continuing to evaluate the safety of other anticoagulants to determine if additional label changes are needed.

RECOMMENDATION: Health care professionals and institutions involved in performing spinal/epidural anesthesia or spinal punctures should determine, as part of a preprocedure checklist, whether a patient is receiving anticoagulants and identify the appropriate timing of enoxaparin dosing in relation to catheter placement or removal. To reduce the potential risk of bleeding, consider both the dose and the elimination

half-life of the anticoagulant:

- For enoxaparin, placement or removal of a spinal catheter should be delayed for at least 12 hours after administration of prophylactic doses such as those used for prevention of deep vein thrombosis. Longer delays (24 hours) are appropriate to consider for patients receiving higher therapeutic doses of enoxaparin (1 mg/kg twice daily or 1.5 mg/kg once daily).
- A postprocedure dose of enoxaparin should usually be given no sooner than 4 hours after catheter removal.
- In all cases, a benefit-risk assessment should consider both the risk for thrombosis and the risk for bleeding in the context of the procedure and patient risk factors.