MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

Hydroxyethyl Starch Solutions: FDA Safety Communication – Boxed Warning on Increased Mortality and Severe Renal Injury and Risk of Bleeding

[Posted 06/11/2013]

FDA分析近期資料指出含hydroxyethyl starch (HES)成分輸注液會提高下列病人之風險：

(i).重症病人(包括敗血症及需於加護病房照護的病人)之死亡及腎臟損傷(導致需進行血液或腹膜透析、腎臟移植)風險。

(ii).大量出血的風險，尤其是進行開心手術而利用體外循環裝置的病人。

建議

醫療人員須注意下列事項:

- 重症病人包括敗血症及需於加護病房照護的病人，不可使用HES輸注液。
- 腎功能不全的病人應避免使用。
- 若發現有腎臟損傷的徵兆時應立即停用 HES 輸注液。
- 先前曾有案例通報於使用HES 輸注液 90 天之後才發生需要進行腎臟移植治療。因此所有使用HES 輸注液的病人皆應持續監控腎功能至少90 天。
- 避免用於進行開心手術而利用體外循環裝置的病人，因可能會造成大量出血。
- 若發現有凝血功能異常的徵兆時應立即停用 HES 輸注液。

[Posted 06/11/2013]

AUDIENCE: Critical Care Medicine, Nephrology, Patient, Pharmacy, Health Professional

ISSUE: FDA has analyzed recent data that indicate an increased risk of (i) mortality and renal injury requiring renal replacement therapy in critically ill adult patients, including patients with sepsis and those admitted to the ICU; and (ii) excess bleeding particularly in patients undergoing open heart surgery in association with cardiopulmonary bypass. Refer to the FDA Safety Communication for more details about the data analysis.

FDA has concluded that HES solutions should not be used in critically ill adult patients, including patients with sepsis and those admitted to the ICU, and a Boxed Warning to include the risk of mortality and severe renal injury is warranted. In addition, FDA has reviewed a meta-analysis of studies conducted in patients undergoing open heart surgery in association with cardiopulmonary bypass and has determined that an additional warning about excessive bleeding is needed in the Warnings and Precautions Section of the package insert.

BACKGROUND: Hydroxyethyl starch (HES) solutions are used for the treatment of hypovolemia (low blood volume) when plasma volume expansion is desired. Recent data have associated the use of these products with an increased risk of severe adverse events when used in certain patient populations.

RECOMMENDATION: Patients should be aware of the risks associated with the use of HES solutions and discuss these risks with their healthcare provider (refer to the FDA Safety Communication for detailed recommendations for patients).

Recommendations for Health Professionals include the following:

- Do not use HES solutions in critically ill adult patients including those with sepsis, and those admitted to the ICU.

- Avoid use in patients with pre-existing renal dysfunction.
- Discontinue use of HES at the first sign of renal injury.
- Need for renal replacement therapy has been reported up to 90 days after HES administration. Continue to monitor renal function for at least 90 days in all patients.
- Avoid use in patients undergoing open heart surgery in association with cardiopulmonary bypass due to excess bleeding.
- Discontinue use of HES at the first sign of coagulopathy.