June

Better Pharmacist Knowledge

Jordan Drug Information and Toxicology Centre 2022

2022

Iodine-containing contrast media (US-FDA 30/3/2022)

- FDA recommends monitoring of pediatric patients from birth through 3 years for the possibility of hypothyroidism or a temporary decrease in thyroid hormone levels following exposure to **iodinated contrast media (ICM)**. Consider evaluating thyroid function within 3 weeks, especially in term and preterm neonates.
- Thyroid dysfunction characterized by hypothyroidism or a temporary decrease in thyroid hormone level has been reported after a single exposure and multiple exposures to ICM.
- Pediatric patients from birth through 3 years warrant closer monitoring to prevent an underactive thyroid during early life that may harm motor, hearing and cognitive development and may require transient T4 replacement therapy.
- Certain pediatric patients are at increased ***risk, including newborns and those having very low birth weight, prematurity, or the presence of cardiac or other conditions such as those requiring care in neonatal or pediatric intensive care units***. Patients with cardiac conditions may be at greatest risk since they often require high doses of contrast during invasive cardiac procedures such as catheterization and computed tomography (CT). [1]

Amiodarone; advice for healthcare professional (MHRS 15 March 2022)

Amiodarone has been associated with serious and potentially life-threatening side effects; particularly of the lung, liver, and thyroid gland. We remind healthcare professionals that patients ***should be supervised and reviewed regularly during treatment***. Lung problems may have slow onset but then progress rapidly. Computed tomography scans may help to confirm a suspected diagnosis of pulmonary toxicity.

Advices for healthcare professionals:

- Amiodarone can cause serious adverse reactions affecting the eyes, heart, lung, liver thyroids gland, skin and peripheral nervous system.
- Review regularly patients ***on long-term amiodarone treatment***; some of these reactions may be life-threatening but onset can be delayed.
- ***Check liver and thyroid function before treatment, and at 6-monthly intervals***; thyroid function should also be monitored for several months after discontinuation.
- Although routine lung imaging is not necessary to patients taking amiodarone long-term, make patients aware of the need to seek advice ***if they have new or worsening respiratory symptoms and consider using computerized tomography (CT) scans if pulmonary toxicity is suspected. [2]***

Haloperidol: Reminder of risks when used in elderly patients for the acute treatment of delirium (JFDA 3/1/2022)

We remind healthcare professionals that elderly patients are at an increased risk of adverse neurological and cardiac effects when being treated with haloperidol for delirium. ***The lowest possible dose of Haloperidol should be used for the shortest possible time*** and ***cardiac and extra pyramidal adverse effects should be closely monitored***.

Advise for healthcare professionals:

- Special caution is required when using haloperidol for the acute treatment of delirium in frail, elderly patients.
- Only consider haloperidol for delirium when non-pharmacological interventions are ineffective and no contraindications are present (including Parkinson's disease and dementia with lewy bodies).
- Before initiating treatment, a baseline ECG and correction of any electrolyte disturbances is recommended; cardiac and electrolyte monitoring should be repeated during treatment.
- Monitor for and investigate early any extrapyramidal adverse effects, such as acute dystonia,parkinsonism, tradive dyskinesia, akathisia, hypersalivation, and dysphagia. [3]

References:

1. Iodine-containing contrast media (US-FDA 30/3/2022), accessed online via JFDA website. قسم الإستخدام الرشيد للدواء /اليقظه الدوائيه
2. Amiodarone; advice for healthcare professional (MHRS 15 March 2022), accessed online via JFDA website. قسم الإستخدام الرشيد للدواء /اليقظه الدوائيه
3. Haloperidol: Reminder of risks when used in elderly patients for the acute treatment of delirium, accessed online via JFDA website. قسم الإستخدام الرشيد للدواء /اليقظه الدوائيه

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Switching between levothyroxine preparations (April 2022)

Although clinicians and patients may have concerns about switching between synthetic levothyroxine products, switching is generally not a clinical problem. In a comparative effectiveness study evaluating changes in thyroid-stimulating hormone (TSH) levels after switching or not switching between generic levothyroxine products in 2780 propensity-matched patient pairs, the proportion of individuals with TSH levels within the normal range was similar in nonswitchers and switchers. If a switch from one manufacturer to another is made by the pharmacy and the patient is concerned regarding equivalent efficacy of the preparations, or if maintaining the serum TSH within a narrow range is important (eg, thyroid cancer treatment), we measure a serum TSH six weeks after changing preparations to document that the serum TSH is still within the therapeutic target. [4]

Increased bleeding with apixaban and systemic fluconazole (May 2022)

Direct oral anticoagulants (DOACs) have fewer drug interactions than warfarin, but interactions do occur. In a large series involving nearly 100,000 individuals receiving a DOAC, individuals receiving **apixaban plus fluconazole**, a moderate inhibitor of the P450 cytochrome CYP3A4, had a 3.5-fold increased risk of bleeding compared with periods when they were receiving apixaban without fluconazole. The increase was greatest in gastrointestinal bleeding requiring hospitalization. ***The risk was only seen with systemic fluconazole plus apixaban; it did not occur with topical fluconazole plus apixaban or systemic fluconazole plus another DOAC***. This study highlights the importance of possible drug interactions and of considering alternatives that might be equally effective, such as topical therapy. [5]

Safety of intravenous (IV) iron (April 2022)

In two new observational studies evaluating >200,000 iron infusions, the safety of intravenous (IV) iron was evaluated using case definitions of anaphylaxis or infusion reaction based upon billing codes or chart review. In one study, administration of antihistamines and other anaphylaxis treatments was used as a surrogate for an infusion reaction. Overall, rates of anaphylaxis were extremely low (from 0.0005 to 0.098 percent). ***However, these are likely overestimates since antihistamines were sometimes administered as premedication before the IV iron infusion, rather than after the infusion in response to a reaction.***

In general, the availability of IV iron formulations with improved safety profiles has lowered the threshold at which many patients would consider switching from an oral to an IV iron preparation. *[6]*

Treatment of chronic hypertension in pregnancy (April 2022)

For pregnant patients with nonsevere chronic hypertension, we recommend antihypertensive treatment. Traditionally, only severe chronic hypertension (blood pressure **[BP] ≥160/110 mmHg**) has been treated in pregnancy because of fetal safety concerns and lack of evidence of maternal benefit. In the Chronic Hypertension and Pregnancy trial, over 2400 pregnant people with nonsevere chronic hypertension (≥140/90 mmHg) were randomly assigned to active treatment (initiating/continuing antihypertensive treatment to keep BP <140/90 mmHg) or usual care (antihypertensive treatment only for BP ≥160/105 mmHg). Active treatment resulted in an 18 percent relative reduction in a composite adverse pregnancy outcome, including preeclampsia with severe features and medically indicated preterm birth <35 weeks, with no adverse fetal effects. Based on this trial, we now recommend antihypertensive treatment for pregnant patients with chronic hypertension to keep BP <140/90 mmHg. We prefer labetalol or extended-release nifedipine. [7]

US-FDA and EMA recommendations regarding Hydroxyethyl Starch (HES) (EMA 25 Feb 2022)

US-FDA Recommendations:

Changes to the boxed warning are warranted to highlight the risk of ***mortality, kidney injury, and excess bleeding, as well as to include a statement that HES products should not be used unless adequate alternative treatment is unavailable.***

EMA Recommendations:

- The marketing authorizations of HES solutions for infusion are being recommended for suspension because of the risk of kidney injury and death in certain patient populations, including critically ill patients and patients with sepsis.
- The latest drug utilization study shows that HES solutions for infusion continue to be used outside the recommendations included in the product information, which still exposes certain patient populations to serious risk.
- Treatment alternatives are available and should be selected according to clinical guidelines. [8]

References:

4. General drug therapy: Switching between levothyroxine preparations (April 2022), accessed online via uptodate.
5. Increased bleeding with apixaban and systemic fluconazole (May 2022), accessed online via uptodate.
6. Safety of intravenous (IV) iron (April 2022), accessed online via uptodate.
7. Treatment of chronic hypertension in pregnancy (April 2022), accessed online via uptodate
8. US-FDA and EMA recommendations regarding Hydroxyethyl Starch (HES) (EMA 25 FEB 2022), accessed online via JFDA website. قسم الإستخدام الرشيد للدواء /اليقظه الدوائيه

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