Tanta University
College of Pharmacy
Drug Information and
Control Center

Drug & Poison Information Bulletin

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First-Ever ADA Guidance Specifically for Type 1 Diabetes

The American Diabetes Association (ADA) 2014 guided a new pediatric glycemic control target of HbA1c < 7.5% across all pediatric ages replaces previous guidelines that had called for different targets by age (< 8.5% for children aged under 6 years, < 8% for those aged 6 to 12 years, and < 7.5% for adolescents between the ages of 13 and 19 years).

Source: www.medscape.com

INSIDE THIS ISSUE:

Medical & Pharmaceutical News

The 2014 Canadian Hypertension Education Program (CHEP) Recommendations for Treatment of Hypertension

Hypertension with **Ischemic heart disease**

A. Recommendations for hypertensive patients with CAD

1. An ACE inhibitor or ARB is recommended for most patients with hypertension and CAD (Grade A)*.
2. For patients with stable angina, β-blockers are preferred as initial therapy (Grade B). CCBs may also be used (Grade B)*.
3. Short-acting nifedipine should not be used (Grade D)*.
4. For patients with CAD, but without coexisting systolic heart failure, the combination of an ACE inhibitor and ARB is not recommended (Grade B)*.
5. In high-risk patients, when combination therapy is being used, choices should be individualized. The combination of an ACE inhibitor and a dihydropyridine CCB is preferable to an ACE inhibitor and a thiazide/ thiazide-like diuretic in selected patients (Grade A)*.
6. When decreasing SBP to target levels in patients with established CAD (especially if isolated systolic hypertension is present), be cautious when the DBP is ≤ 60 mm Hg because of concerns that myocardial ischemia might be exacerbated (Grade D) *.

B. Recommendations for hypertensive patients who have had a recent myocardial infarction

1. Initial therapy should include a β-blocker and an ACE inhibitor (Grade A)*.
2. An ARB can be used if the patient is intolerant of an ACE inhibitor in patients with left ventricular systolic dysfunction (Grade A)*.
3. CCBs may be used in patients after myocardial infarction when β-blockers are contraindicated or not effective. Nondihydropyridine CCBs should not be used when there is heart failure, evidenced by pulmonary congestion at time of examination or radiography (Grade D)*.

Medical & Pharmaceutical News (cont.)

Hypertension with Stroke

A) Blood pressure management in acute stroke

1-For patients with ischemic stroke ***not eligible for thrombolytic therapy***, treatment of hypertension in the setting of acute ischemic stroke or transient ischemic attack should not be routinely undertaken (Grade D)*.
Extreme BP increases (e.g., SBP > 220 mm Hg or DBP > 120 mm Hg) may be treated to reduce the BP by approximately 15% (Grade D)*, and not more than 25%, over the first 24 hours with gradual reduction thereafter (Grade D)*.
Avoid excessive lowering of BP because this might exacerbate existing ischemia or might induce ischemia, particularly in the setting of intracranial arterial occlusion or extracranial carotid or vertebral artery occlusion (Grade D)*.
Pharmacological agents and routes of administration should be chosen to avoid precipitous decreases in BP (Grade D)*.

2-For patients with ischemic stroke ***eligible for thrombolytic therapy***, very high BP (> 185/110 mm Hg) should be treated concurrently in patients receiving thrombolytic therapy for acute ischemic stroke to reduce the risk of secondary intracranial hemorrhage (Grade B)*.

B) Blood pressure management after acute stroke

1-Strong consideration should be given to the initiation of antihypertensive therapy after the acute phase of a stroke or transient ischemic attack (Grade A)*.
2-After the acute phase of a stroke, BP-lowering treatment is recommended to a target of consistently < 140/90 mm Hg (Grade C)*.
3-Treatment with an ACE inhibitor and thiazide/ thiazide-like diuretic combination is preferred (Grade B)*.
4-For patients with stroke, the combination of an ACE inhibitor and ARB is not recommended (Grade B)*.

About CHEP:
The Canadian Hypertension Education Program is Hypertension Canada's knowledge translation program that targets various healthcare professionals in clinical and community settings, provides annually updated standardized recommendations and clinical practice guidelines to detect, treat and control hypertension.

***Recommendations are graded according to the strength of their underlying evidence ranging from Grade A (strongest evidence, based on high-quality randomized clinical trials) to Grade D (weakest evidence, based on low power, imprecise studies or expert opinion alone).**

Source : Canadian Journal of Cardiology. Volume 30, Issue 5, May 2014.

Medical Safety Updates

Over-The-Counter Topical Acne Products: Drug Safety Communication - Rare But Serious Hypersensitivity Reactions

FDA is warning that OTC topical acne products that are available as gels, lotions, face washes, solutions, cleansing pads, toners, face scrubs, and other products can cause rare but serious and potentially life-threatening allergic reactions such as throat tightness; difficulty breathing; feeling faint; or swelling of the eyes, face, lips, or tongue.

Consumers should also stop using the product if they develop hives or itching.

The hypersensitivity reactions may occur within minutes to a day or longer after product use.

These serious hypersensitivity reactions differ from the local skin irritation that may occur at the product application site, such as redness, burning, dryness, itching, peeling, or slight swelling, that are already included in the Drug Facts labels.

BACKGROUND: Based on the information reported to FDA, it cannot be determined if the serious hypersensitivity reactions were triggered by the acne products' active ingredients, benzoyl peroxide or salicylic acid, the inactive ingredients, or by a combination of both. FDA is continuing to monitor and evaluate this safety issue, and will work with manufacturers regarding any future label changes that would address the risk of severe hypersensitivity reactions.

RECOMMENDATION: Before using an OTC topical acne drug product for the first time, apply a small amount to one or two small affected areas for 3 days to make sure you don't develop any hypersensitivity symptoms. If no discomfort occurs, follow the directions on the Drug Facts label.

Source: www.fda.gov, June 2014.

New safety information regarding the dosage and administration of intravenous ondansetron (ZOFRAN®) in geriatrics (>65 years of age)

Health Canada and GlaxoSmithKline are informing health care providers and patients of new dosing and administration restrictions for intravenous (I.V.) Zofran (ondansetron) to mitigate the risk of QT prolongation in patients older than 65 years of age.

In these patients, the risk of QT prolongation is expected to be greater with faster infusion rates and larger doses.

The dosing restrictions for geriatrics are summarized below:

- -In patients ≥**75** years of age, the initial IV dose must not exceed **8 mg**.
- -In patients <**75** years of age, the initial IV dose must not exceed **16 mg**.
- -Subsequent IV doses must not exceed **8 mg** and may be given 4 and 8 hours after the initial dose.
- -All IV doses must be diluted in 50–100 mL of saline or other compatible fluid.
- -All IV doses must be infused over no less than **15 minutes**.

Source: online lexicomp databases, June 2014.

Medical Safety Updates (cont.)

Do Teething Babies Need Medicine on Their Gums? *No*

The U.S. Food and Drug Administration (FDA) warns that prescription oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death.

Parents and caregivers should follow the American Academy of Pediatrics' recommendations for treating teething pain:

- Use a teething in the refrigerator (not frozen).
- Gently rub or massage the child's gums with your finger to relieve the symptoms.

When too much viscous lidocaine is given to infants and young children or they accidentally swallow too much, it can result in seizures, severe brain injury, and problems with the heart.

In 2014, FDA reviewed **22 case reports** of serious adverse reactions, including deaths, in infants and young children 5 months to 3.5 years of age who were given oral viscous lidocaine 2 % solution for the treatment of mouth pain, including teething and stomatitis, or who had accidental ingestions.

FDA in 2011 previously warned that using OTC benzocaine gels for teething or mouth pain can cause a rare but serious condition called methemoglobinemia. This condition results in a large decrease in the amount of oxygen carried through the blood. It is life-threatening and can result in death .

FDA has continued to receive reports of methemoglobinemia in infants and children associated with OTC benzocaine gels and liquids since the 2011 warning was issued.

Source:* www.fda.gov, *June 2014

Treatment with Docetaxel (Taxotere™) Products May Cause Symptoms of Alcohol Intoxication

- The FDA is warning health care providers and patients that ***Docetaxel**** injection products contain ethanol, which may cause patients to experience symptoms of alcohol intoxication during and after treatment.
- The FDA is revising the labels of all docetaxel drug products to warn about this risk.
- Health care providers should consider the alcohol content of docetaxel products when prescribing or administering the drug to patients, particularly in those whom alcohol intake should be avoided or minimized and when using it in conjunction with other medications.

Precautions: Patients should avoid driving, operating machinery, or performing other activities that are dangerous for one to two hours after docetaxel infusion.

***Docetaxel:** Indicated in Breast Cancer, Non-Small Cell Lung Cancer, Prostate Cancer, Gastric Adenocarcinoma, Head And Neck Cancer.

Source:* online lexicomp databases, *June 2014

New approved drugs

FDA Approves Inhaled Insulin

[June 27, 2014] The FDA has approved inhaled insulin to treat type 1 and type 2 diabetes. The insulin, called *AFREZZA*, is rapid-acting insulin and is meant to be taken at mealtime or soon after.

It is a first-in-class, ultra rapid-acting mealtime insulin therapy. It is a drug-device combination product, consisting of AFREZZA Inhalation Powder single use dose cartridges, and the small, discreet and easy-to-use AFREZZA inhaler. It offer glycemic control with lower risk of hypoglycemia, less weight gain and an alternative to injections.

Afrezza carries a warning as it may cause a sudden tightening of the chest. It is not recommended for people with asthma or COPD. It is also not recommended for people that smoke or for the treatment of diabetic ketoacidosis.

Source: www.fda.gov

FDA Approves BELSOMRA® (suvorexant) for the Treatment of Insomnia

[August 13, 2014] The U.S. Food and Drug Administration approved Belsomra (suvorexant).

BELSOMRA is a highly selective antagonist for orexin receptors and it is the first approved drug of this type. Orexin is a neurotransmitter found in a specific part of the brain that can help keep a person awake.

BELSOMRA (suvorexant) is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

The recommended dose of BELSOMRA is 10 mg, taken no more than once per night and within 30 minutes of going to bed, with at least 7 hours remaining before the planned time of awakening. The total dose should not exceed 20 mg once daily.

Source: www.fda.gov , www.rxlist.com

Beleodaq Approved for Aggressive non-Hodgkin Lymphoma

[July 3, 2014] Beleodaq (belinostat) has been approved by the U.S. Food and Drug Administration to treat peripheral T-Cell lymphoma (PTCL), a rare and aggressive form of non-Hodgkin lymphoma. Beleodaq is designed to inhibit immune cells called T-cells from becoming cancerous, The drug is intended for people whose cancer has returned or who didn't respond to a prior therapy.

What is PTCL and How to treat it ?

PTCL is a rare and often aggressive (fast-growing) cancer that develops from white blood cells called T-lymphocytes, or T-cells. In cases when these cells start to grow too quickly and resist dying, they can accumulate in the body. This is what causes cancer.

Treatment Options:

PTCL is most often treated with a combination of chemotherapies. Two common chemotherapy combinations for PTCL are CHOP (cyclophosphamide,doxorubicin, vincristine, prednisone) and EPOCH (etoposide, vincristine,doxorubicin, cyclophosphamide,prednisone).

Pralatrexate (Folotyn) was the first drug the FDA approved specifically for PTCL patients. Pralatrexate is approved for treating patients with relapsed or refractory PTCL. In 2011, the FDA approved romidepsin (Istodax) injection for the treatment of PTCL in patients who have received at least one prior therapy.

Source: www.fda.gov

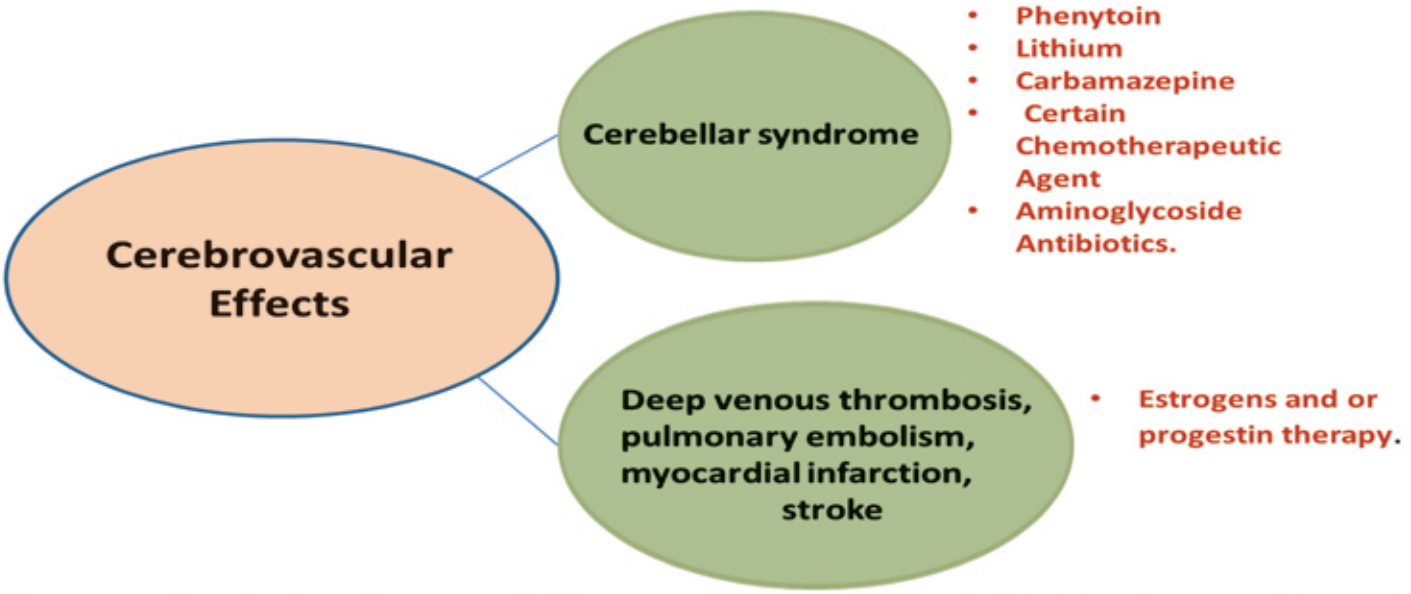
Drug-Induced Neurologic Conditions

Some neurological compliance of commonly prescribed drugs

The emergence of new neurologic side effects of drugs heightens the challenges prescribers face when considering drug therapy. These side effects can result in potential misdiagnoses, including false psychiatric diagnoses, in the case of some drugs. Unexpected and unpredictable drug interactions can result in a confusing range of symptoms that may be identified as a new medical condition.
Changes in the central nervous system (brain, spinal cord) or peripheral nerves can cause a wide variety of symptoms, including loss of coordination and muscle strength, numbness, loss of consciousness, seizures, and paralysis .In July 2013, the FDA added a black box warning to the antimalarial drug mefloquine about serious neurologic side effects, including dizziness, loss of balance, and tinnitus.

Drug induced cerebrovascular disorders

Cerebrovascular effects includes cerebellar syndrome, deep venous thrombosis, pulmonary embolism, myocardial infarction, and stroke.
Cerebellar syndrome is a consequence of the disruption of normal function of the brain region that is responsible for coordination and balance. In addition to loss of coordination, some patients may experience dysarthria and nystagmus. Many cases are reversible; however, permanent cerebellar syndrome can result, especially with administration of high doses and concurrent use of agents conferring risk, such as lithium plus antipsychotics.



Deep venous thrombosis, pulmonary embolism, myocardial infarction, and stroke have been reported with the use of estrogens and/or progestin therapy. While hormone replacement therapy is no longer routinely prescribed for menopausal women, the risk of neurologic side effects must be considered in women taking injectable hormone therapies or oral contraceptives.

A significantly increased incidence of transient ischemic attack, cerebral ischemia, unspecified cerebrovascular disorders, and stroke has been reported versus placebo in patients older than 73 years who have dementia-related psychosis. Individual stroke risk factors such as smoking, hypertension, and diabetes increase the risk of this adverse neurologic event.

Drug-Induced Neurologic Conditions

Drug induced seizure

Certain drugs can induce seizures in patients without a preexisting seizure disorder. Many substances can lower the seizure threshold, The risk of drug-induced seizure increases when multiple agents with potential risk are administered concomitantly. The withdrawal of drugs such as benzodiazepines also may provoke seizures. Symptoms associated with drug-induced seizures are similar to those of non–drug-related seizures. The majority of seizures induced by drugs present as generalized tonic-clonic seizures. A number of patient factors further increase the risk of seizure precipitation, including age, metabolic abnormalities (e.g., electrolyte imbalance), and head trauma.

Some Drugs induced seizure

Medication for mental health disorders

- Buspirone, Chlorpromazine, Clozapine, Haloperidol, Tricyclic antidepressant, Lithium.
- Stopping use of Barbiturates after regular use can cause seizures.

antibiotics

- Patients who take too much of Ceftazidime, Ciprofloxacin or Imipenem may have seizures.
- Ingesting high levels of Penicillin can also trigger seizures.

Pain medication

- Tramadol and Meperidine, Indomethacin.
- Patients who stop using pain medications, like Gabapentin and Morphine, after large doses may have seizures.

Recreational Drugs

- Using certain recreational drugs can cause seizure in some people e.g. Amphetamine.
- An overdose of Cocaine can also cause seizures.
- People who stop using Alcohol after heavy and regular use can have seizures.

Drug induced neuroleptic malignant syndrome

Neuroleptic malignant syndrome (NMS) is a drug-induced neurologic disorder caused by neuroleptic and antipsychotic drugs. Muscular rigidity, autonomic instability, fever, and changes in cognition (e.g., delirium) are hallmarks of NMS.

Drug induced NMS

- Neuroleptics and antipsychotics can cause NMS when administered as single agents; however, the risk increases when they are given concurrently
- Conventional first-generation antipsychotics (e.g., chlorpromazine and haloperidol.)
- Drugs with dopamine-antagonist activity (e.g., metoclopramide).
- Abrupt discontinuation of dopamine agonists such as levodopamay increase the risk of NMS

Source :www.medscape.com, www.livestrong.com

New Diagnostic Tools

Eye Test May Diagnose ADHD, Predict Treatment Response

A simple test examining involuntary eye movements may provide an objective way to tell whether individuals have attention-deficit/hyperactive disorder (ADHD)* and whether stimulant medication will be an effective treatment, new research suggests.

Investigators observed increased **microsaccades** and blink rates** in adults with ADHD, in a study published in the August issue of Vision Research.
They found that unmedicated ADHD patients had significantly higher rates of eye blinks and microsaccades compared with control participants. This effect was largest in the peristimulus period "where eye movements should be suppressed because they could interfere with the task". In addition, stimulant medication had a "striking effect" on involuntary eye movements, with full normalization of the microsaccade rate to the control level and partial normalization of blink rates, mainly in the peristimulus interval.

***Attention-deficit/hyperactivity disorder (ADHD) :** is a mental health condition exhibited by difficulty maintaining attention, hyperactivity and impulsive behavior. Adult ADHD symptoms can lead to unstable relationships, poor work or school performance, and low self-esteem. ADHD always starts in early childhood, but in some cases it's not diagnosed until later in life .
****Microsaccades:** are a kind of fixational eye movement. They are small, jerk-like, involuntary eye movements.
Source : www.medscape.com (August 20, 2014) , www.mayoclinic.com

Upcoming Conferences

- **Saudi Gastroenterology Association 13th Conference & 2nd SASLT Meeting 2014**
  November 25, 2014 - November 27, 2014,
  Al khobar , Saudi Arabia

- **Arab Society for Pediatric Endocrinology 2nd Annual Conference 2014**
  November 6, 2014 - November 8, 2014,
  Abu Dhabi , United Arab Emirates

- **5th International Diabetic Foot Conference 2014**
  November 13 , 2014 – November 14 , 2014, **Dubai , UAE , United Arab Emirates**

- **16th International Workshop on GI Therapeutic Endoscopy,**
  December 13 , 2014 – December 14 , 2014, Make your reservation before Friday, 5th of December 2014,
  @ Conrad International Hotel, Cairo, Egypt

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