مركز معلومات الدوية والسموم
Drug & Poison Information Center

Drug & Poison Information Center BULLETIN

جامعة الملك سعود
King Saud University

College of Pharmacy
Drug and Poison Information Center

VOLUME 35 ISSUE 4
Oct –Dec 2017

FDA Approves New CLIA-Waived CBC Test for Faster Results

A CBC test is used to evaluate a patient's blood levels, in the current health care setting, CBC can experience at least a 24-hour wait for test results, The FDA reviewed data from a 582 samples collected. The study compared the XW-100 test results collected by non-medical personnel in CLIA-waived settings to a hematology analyzer The FDA granted premarket clearance and a CLIA waiver for the XW-100 Automated Hematology Analyzer.

Source; https://www.fda.gov

In this issue .. ..

Medical News

Low vitamin D Level may raise risk of kidney failure – results form a new research

New research, conducted by scientists at the Johns Hopkins University School of Medicine in Baltimore, found that low vitamin D level raises the risk of organ damage and renal disease in people with lupus . Lupus is an autoimmune disease characterized by inflammation throughout the body. This occurs because the body does not recognize its own tissues and starts attacking them. The disease can affect various organ systems, from the cardiovascular and immune systems to vital organs such as the lungs and the kidneys.

Studying vitamin D levels in lupus patients

A team of researchers from University School of Medicine in Baltimore, examined the clinical data available on 1,392 lupus patients, 92 percent of whom were female. On average, the patients were 47.3 years old.

The researchers had access to the patients' vitamin D levels when they first visited the doctor, as well as to the state of their organs and tissues during the follow-up visits. Levels of the vitamin were assessed using 25-hydroxy vitamin D which is a common and accurate way of ascertaining vitamin D levels. Based on the first measurements of vitamin D, patients were grouped into two arms: patients with less than 20 nanograms per milliliter (ng/ml) of 25-hydroxy vitamin D and others with more than 20 ng/ml. Overall, 27.3 percent of the patients had deficient levels of vitamin D at their first medical visit. Using the Systemic Lupus International Collaborating Clinics/American College of Rheumatology (SLICC/ACR) Damage Index, the researchers evaluated the "risk of lifetime organ damage."

Medical News (cont..)

Low vitamin D may predict renal failure

The study found that lupus patients with deficient levels of vitamin D had the highest relative risk of renal damage. These patients were also at a higher risk of skin damage and total organ damage. The study results also found no association with damage to any of the other organs considered. Low vitamin D associated with total organ damage and with end-stage renal disease. Surprisingly, the results also revealed that low vitamin D did not associate with musculoskeletal damage including osteoporotic fractures. Results of the study also had shown that supplementing vitamin D reduces urine protein , which is the best predictor of future renal failure. The author of the study also suggests that vitamin D supplementation may be a valid pathway for the prevention of renal damage in lupus.

Supplementary vitamin D is very safe, and It helps to prevent one of the most dreaded complications of lupus, .It has likely a role in preventing blood clots and cardiovascular disease as well. Vitamin D supplementation, which can reduce proteinuria, should be a part of the treatment plan for lupus patients.

Source: https://www.medicalnewstoday.com

Increased Incidence of Vascular Injury in Obese Patients with Knee Dislocations – results from a cohort study

Obesity greatly increases the complications and costs of care. A new study of more than 19,000 knee dislocation cases in the U.S. between 2000 and 2012 provides a painful indication of how the nation's obesity epidemic is changing the risk, severity and cost of a traumatic injury.

Knee dislocations occur when the knee is badly disrupted because of multiple torn ligaments in the joint. Typically, this happens in vehicle crashes or contact sports like football. An increase in knee dislocations among obese patients with an increased risk of vascular injury to the main artery that runs down the leg behind the knee. To understand what's going on more comprehensively, they analyzed records in the Nationwide Inpatient Sample, a database of patients who've had hospital stays. Over the study period, they found that obese or morbidly obese patients made up an increasing share of knee dislocation patients, rising to 19% of patients in 2012 compared to just 8% in 2000. With rising rates of obesity in the United States (U.S.), the burden of knee dislocations in this population remains unknown.This national epidemiologic study was designed to analyze the association of obesity with closed knee dislocation and vascular complications. A Retrospective cohort study design was used. The de-identified Nationwide Inpatient Sample (NIS) database was utilized to access U.S. inpatient data from 2000 to 2012

2012. Outcome measures included hospital length of stay (LOS), amputation, and inpatient hospitalization charge. From 2000-2012, a total of 19,087 knee dislocations were identified, including 2,265 in overweight/obese patients (11.9%). The annual incidence of knee dislocations reported in patients diagnosed as either obese or morbidly obese increased over the 13-year time period ($p<0.0001$). The overall average rate of vascular injury requiring intervention was 5.63%; while 7.2% of obese patients and 11.3% of morbidly obese patients with knee dislocations ($p<0.0001$) sustained a vascular injury requiring intervention. The average length of stay and amputation rate for obese and morbidly obese patients that sustained a knee dislocation was not statistically different from non-obese patients when vascular injury was controlled. When patients with a vascular injury were excluded, obese and morbidly obese patients that sustained a knee dislocation had higher average cost of hospital stay, than non-obese patients ($p = 0.0262$). This study demonstrates significant increases in costs of stay with obese patients sustaining knee dislocations when compared to normal weight knee dislocation patients. Vascular injuries were found to be far more common in obese and morbidly obese patient groups than non-obese patients. Providers should be on high alert when managing knee dislocations in obese patients as a significant number require prompt vascular intervention.

Source: ***Joey Johnson, Justin Kleiner, Stephen Klinge, Philip McClure, Roman Hayda, Christopher Born.*** *Increased Incidence of Vascular Injury In Obese Patients with Knee Dislocations.* **Journal of Orthopaedic Trauma,** ***2017.***

Warfarin May Prevent Cancer

Warfarin is a medication used to reduce the risk of heart attack or stroke. A new study, however, suggests that the drug may also help to reduce the risk of cancer, particularly for people aged 50 and older. The study included data from 1,256,725 individuals, and collected from participants who used warfarin versus who didn't use warfarin during the period from January 2004 to December 2012. Cancer incidence among the subjects was assessed from January 2006 to December 2012. Of the study participants, 92,942 individuals were taking warfarin. **The researchers found that individuals who used warfarin had 16% reduced risk of all cancers, compared with people who did not use the drug.** Looking at organ-specific sites, warfarin use was linked with 31% reduced risk of prostate cancer, 20% reduced risk of lung cancer, and 10% lower risk of breast cancer. Additionally, the researchers assessed how warfarin use influenced the risk of cancer development in a subgroup of individuals who were prescribed the drug for atrial fibrillation or atrial flutter. Results revealed that these individuals were at lower risk of cancer development overall, and they were also less likely to develop prostate, lung, breast, and colon cancers. In conclusion study confirms that warfarin provides a possible cancer protection, a finding that may have important implications for choosing medications for patients who need anticoagulation.

Source ; By Honor Whiteman

Simultaneous Use of Entresto and angiotensin converting enzyme ACE Inhibitors Can Lead to Serious Outcomes

Entresto (sacubitril/valsartan) is an angiotensin II receptor-neprilysin inhibitor (ARNI) used to reduce the risk of cardiovascular death and hospitalization in patients with chronic heart failure and reduced ejection fraction. Entresto is contraindicated with concomitant use of angiotensin converting enzyme (ACE) inhibitors because the inhibition of neprilysin from the sacubitril component in Entresto combined with an ACE inhibitor increases the risk of angioedema. Also, the dual renin-angiotensin-aldosterone system blockade that occurs when valsartan is combined with ACE inhibitors increases the risk of hypotension, acute kidney injury, and hyperkalemia. Thus, Entresto should not be administered within 36 hours of switching from or to an ACE inhibitor.

The most common adverse events reported due to this drug interaction were angioedema, hyperkalemia, acute kidney injury, and hypotension. Entresto is used to lessen morbidity and mortality, and replaces an ACE inhibitor or ARB in patients with chronic symptomatic heart failure (NYHA class II or III) with a reduced ejection fraction who tolerate an ACE inhibitor or ARB. Due to the previous standard of care, many patients starting Entresto are already taking ACE inhibitors. This could lead to serious adverse events if the ACE inhibitor is not discontinued, or if the patient continues taking the previously prescribed ACE inhibitor at home. These errors may be related to the lack of familiarity with Entresto.

Table 1. ACE inhibitors/ARBs to avoid with Entresto

ACE Inhibitors	ARBs
benazepril (**LOTENSIN**)	azilsartan (**EDARBI**)
captopril	candesartan (**ATACAND**)
enalapril (**VASOTEC**)	
enalaprilat	eprosartan (**TEVETEN**)
fosinopril	
lisinopril (**PRINIVIL, ZESTRIL**)	irbesartan (**AVAPRO**)
	losartan (**COZAAR**)
moexipril	olmesartan (**BENICAR**)
perindopril (**ACEON**)	
quinapril (**ACCUPRIL**)	telmisartan (**MICARDIS**)
ramipril (**ALTACE**)	
trandolapril (**MAVIK**)	valsartan (**DIOVAN**)

SAFE PRACTICE RECOMMENDATIONS: For Prescribers, Pharmacists, and Nurses:

- Prior to prescribing Entresto, ensure that patients are not already taking an ACE inhibitor. For patients taking an ACE inhibitor, ensure that it is stopped and allow for a 36-hour washout period prior to starting Entresto.
- Work with information technology (IT) staff to create and/or enable order entry system alerts to warn against the concomitant use of Entresto and ACE inhibitors when both of these drugs have been prescribed for the patient. If possible, configure the alert to continue for 36 hours after Entresto or the ACE inhibitor has been discontinued.
- Before dispensing Entresto, review patients' medication regimens.
- Educate and explain patients about the importance of not taking Entresto and ACE inhibitors together.
- Conduct a thorough medication reconciliation (on admission and at discharge) to ensure that patients who are prescribed Entresto were not taking an ACE inhibitor or ARB in the past or not being both prescribed upon discharge from the hospital.

Source ; https://www.ismp.org

Medication Safety Updates

Health Care Professionals and Patients Not to Use Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Manufactured by Foshan Flying Medical Products

The U.S. Food and Drug Administration is alerting health care professionals and patients not to use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co. Ltd., located in China, due to the lack of sterility assurance and other quality issues. Alcohol pads and antiseptic towelettes are used by health care professionals and patients for preparation of the skin prior to injection, as well as in first aid to decrease germs in minor cuts, scrapes and burns. The use of these alcohol pads and antiseptic towelettes could cause infections.

Patients, health care facilities and pharmacies that have alcohol pads and antiseptic towelettes labeled by Total Resource or Simple Diagnostics should immediately stop using them and discard the products. Patients should contact a doctor if they experienced any adverse reactions after using these products

Source: https://www.fda.gov/Drugs/DrugSafety

FDA Confirms Increased Risk of Leg and Foot Amputations with the Diabetes Medicine Canagliflozin (Invokana, Invokamet, Invokamet XR)

U.S. Food and Drug Administration (FDA) is alerting the public about interim safety results from an ongoing clinical trial that found an increase in leg and foot amputations, mostly affecting the toes, in patients treated with the diabetes medicine canagliflozin (Invokana, Invokamet). However, it has not been determined whether canagliflozin increases the risk of leg and foot amputations. Canagliflozin is sodium-glucose cotransporter-2 (SGLT2) inhibitors and is used with diet and exercise to lower blood sugar in adults with type 2 diabetes. In the ongoing Canagliflozin Cardiovascular Assessment Study, clinical trial, the trial's independent data monitoring committee (IDMC) identified an increased risk of leg and foot amputations. The amputations occurred about twice as often in patients treated with canagliflozin compared to patients treated with placebo.

Patients should not stop or change their diabetes medicines without first talking to their health care professional. Patients taking canagliflozin should notify their health care professionals right away if they notice any new pain or tenderness, sores or ulcers, or infections in their legs or feet.

Health care professionals should follow the recommendations in the canagliflozin drug labels, and monitor patients for the signs and symptoms of suspected leg or foot injury or infection.

Source: https://www.fda.gov/Drugs/DrugSafety.

FDA Approves Vyzulta (latanoprostene bunod) Ophthalmic Solution for Open-Angle Glaucoma, Ocular Hypertension

U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for Vyzulta (latanoprostene bunod ophthalmic solution, 0.024%). Vyzulta, the first prostaglandin analog with one of its metabolites being nitric oxide (NO), is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Following topical administration, Vyzulta, a once daily monotherapy with a dual mechanism of action, works by metabolizing into two moieties, latanoprost acid, which primarily works within the uveoscleral pathway to increase aqueous humor outflow, and butanediol mononitrate, which releases NO to increase outflow through the trabecular meshwork and Schlemm's canal. The most common ocular adverse events include conjunctival hyperemia, eye irritation, eye pain and instillation site pain. The safety and efficacy of Vyzulta has been well-established through multiple clinical studies, which have demonstrated positive results, including statistically significant differences in IOP lowering compared to timolol and latanoprost. As one molecule with a dual mechanism of action, Vyzulta provides a new treatment option that works to reduce IOP by increasing the outflow through both the trabecular meshwork and the uveoscleral pathways.

Source: https://www.drugs.com

FDA Approves Calquence (acalabrutinib) for Adults with Mantle Cell Lymphoma

The U.S. Food and Drug Administration today granted accelerated approval to **Calquence** (acalabrutinib) for the treatment of adults with mantle cell lymphoma .Mantle cell lymphoma is a rare and fast-growing type of non-Hodgkin lymphoma and, according to the National Cancer Institute at the National Institutes of Health, represents 3 to 10 percent of all non-Hodgkin lymphoma cases in the U.S. Mantle cell lymphoma is a cancer of the lymph system, which is part of the body’s immune system and is made up of lymph tissue, lymph nodes, the spleen, thymus, tonsils and bone marrow. By the time mantle cell lymphoma is diagnosed, it usually has spread to the lymph nodes, bone marrow and other organs.Common side effects of Calquence include headache; diarrhea; bruising; fatigue and muscle pain (myalgia); and reduced levels of red blood cells (anemia), platelets (thrombocytopenia) and neutrophils (neutropenia) in the blood. Serious side effects include bleeding (hemorrhage), infections and irregular heartbeat (atrial fibrillation). Additional cancers, known as second primary malignancies, have occurred in some patients taking Calquence.

Source: https://www.drugs.com

توضيح من "الغذاء والدواء" بخصوص مستحضر Trulicity الذي يحمل الاسم العلمي Dulaglutide

03-Oct-2017

مستحضر (Trulicity) واسمه العلمي (Dulaglutide)، مسجل لدى الهيئة العامة للغذاء والدواء ويستخدم لتحسين مستوى ضبط السكر في الدم عند مرضى السكري من النوع الثاني .

- المستحضر آمن وفعال إذا استخدم حسب إرشادات الطبيب والنشرة المرفقة .
- يمكن استخدام المستحضر بمفردة أو كدواء إضافي مع أدوية السكر الأخرى التي قد يتطلب مراجعة جرعاتها منعاً لحدوث هبوط سكر الدم .
- لاينصح بإستخدام المستحضر في الحالات التالية :
(خط علاج أولي لداء السكري، المرضى المصابون بالتهاب البنكرياس، مرضى السكري من النوع الأول) .
- لايعتبر المستحضر بديلاً عن الانسولين .
- يحذر من استخدامه لدى الأشخاص المصابين بسرطان الغدة الدرقية وسرطانات الغدد الصماء أو لديهم تاريخ عائلي بالإصابة به .

تهيب الهيئة بجميع الأطباء والصيادلة والممارسين الصحيين بشكل عام عدم الإعلان عن المستحضرات الدوائية بصورة مخالفة لنظام المنشآت والمستحضرات الصيدلانية .

المصدر: *الهيئة العامة للغذاء والدواء .*

نصائِح صحيَّة : ما هي الأمور الصحية التي يمكن استشارة الصيدلي فيها ؟

03-Nov-2017

كثيراً ما يكون الصيدلي أول شخص يلجأ إليه المرضى عند ظهور الأعراض عليهم، كما إن الناس كثيراً ما يلجؤون إليه لاستشارته حول المسائل الصحية المختلفة. ولذا فإنه من الضروري معرفة حدود ما يمكن استشارة الصيدلي به، وتعزيز الصلة به كونه الملاذ الأول لتقديم الرعاية الصحية في كثير من الأحيان.

وفي هذا الصدد، تُقدم المراكز الأمريكية لمكافحة الأمراض والوقاية منها بعض الأمثلة للاستشارات التي يمكن للصيدلي تقديمها لزوار الصيدلية:

- **جميع المعلومات المتصلة بالأدوية:** من حيث استطباباتها، وفعاليتها، وتأثيراتها الجانبية، وطريقة تناولها، وغير ذلك.
- **اختيار بدائل تجارية لنفس الدواء:** يمكن للصيدلي اقتراح بدائل أقل ثمناً لنفس المادة الدوائية.
- **تقديم نصائح حول أمان الأدوية التي يمكن تناولها بدون وصفة طبية:** سواءً عند تناولها بمفردها، أو تناولها مع أدوية أخرى، ومدى ملائمتها للمرأة الحامل أو الأشخاص المصابين بحالات مرضية محددة.
- **مساعدة المرضى في القيام ببعض الفحوص الروتينية:** مثل قياس ضغط الدم، أو قياس مستوى السكر، وتقديم نصائح حول تلك الحالات وتدبيرها.

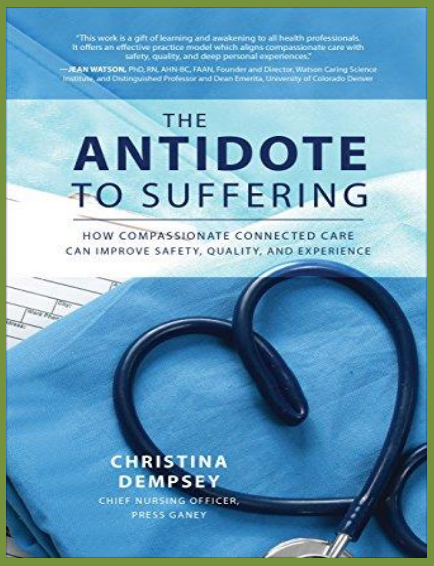
المصدر: *موسوعة الملك عبد الله بن عبد العزيز العربية للمحتوى الصحي .*

Scientific Books: New Release

The Antidote to Suffering: How Compassionate Connected Care Can Improve Safety, Quality, and Experience author (Christina Dempsey)

An indispensable guide to reducing the suffering—of patients and caregivers alike—and to improving healthcare delivery for all. *The Antidote to Suffering* is the first book to explore the pervasiveness of suffering in our healthcare system, and to provide the strategies and tools to:

Identify and measure suffering throughout your organization create a system in which every clinical response is informed by compassion. Operationalize staff behavior to promote meaning and purpose. Increase productivity by building a culture of collaboration reducing human suffering isn't just a moral imperative for healthcare providers. It's a practical way to improve organizations and fix our broken system.



If you want to receive the DPIC bulletin in your E-mail please contact us via: *rayalmansour @ksu.edu.sa*

Upcoming Conferences

- 6th - 8th December 2017. 18th International Conference on Medicinal Chemistry and Computer Aided Drug Designing and Smart Drug Delivery at the Embassy Suites by Hilton Dallas Park Central, USA.
- 11th - 13th December 2017. International Conference on Nanotechnology. At Crowne plaza, Dubai in UAE.
- 14th - 16th December 2017. International Conference on Toxicology and Clinical Pharmacology, Rome, Italy, Europe
- 14th - 16th December 2017. **26th International Conference on Clinical Diabetes** in Rome, Italy, UK

Editorial Board

Address / Correspondence:

Drug & Poison Information Center, College of Pharmacy, King Saud University. P.O. Box 2457 Riyadh 11451, Saudi Arabia. Tel: 4677352, 4677353, 4677354 Fax: 4676229
E-mail:*rayalmansour@ksu.edu.sa*

ISSN: 1319 – 43021319 – 4302 :ردمد