

January 2016

Volume 6 Issue 1 Marci Wood, Editor

Editorial

Resolutions

By Marty Irons

Happy New Year!

Often we find ourselves at this time of year taking stock of our situation in life and resolving to make changes for the next twelve months. Frequently these resolutions take the form of goals to change or improve our own health.

Recently I was reading an endocrine journal. The majority of the seventy or so articles presented summaries of studies involving the use of medications. Only one study looked at whether a specific behavior (standing vs. sitting throughout the day) could influence health. In community care, the majority of the medications we dispense are to treat diagnoses that are the result of lifestyle rather than acute situations or infectious disease. Though we labor hard to ensure prescriptions are filled and dispensed correctly, how much do we do to encourage healthier behaviors in our patients?

Changing behaviors is difficult for us all. Like New Year's resolutions, change is easiest when it is simple to implement. For our patients, if we can convince them to substitute water for other beverages, cut back or quit smoking, use smaller dinner plates, always have some 'greens' with dinner, increase the number of footsteps daily, etc., than we can help them improve their health. What will you do to help your patients besides providing medications in 2016? I look forward to hearing of your efforts!

May 2016 be a healthy and professionally rewarding year for both you and your patients!

Marty

Marty Irons, RPh, CDE Publisher

Board of Pharmacy Online Reference Policy

The Vermont Board of Pharmacy has provided some clarification regarding acceptable online references when checking for drug interactions. An online reference is acceptable in place of a hard copy only if made known and accessible to every pharmacist. The reference (whether online or a hard copy) must be complete as defined by the Board as including: State and federal drug laws relating to pharmacy practice, a current manual of drug interactions equivalent to Hansten's or Drug Facts with quarterly updates, Current Facts and Comparisons with monthly updates or its equivalents, current reference on pediatric dosages, and current reference for herbals and alternative medicines if these are sold at the pharmacy.

Examples of references acceptable to the Board include: Cerner Multum, Clinical Pharmacology, Epocrates, Facts & Comparisons, and Hansten and Horn: Drug Interactions. The Board may also review a reference for equivalence to Hansten's or Drug Facts.

The full rule can be found online. Any questions can be directed to the Board of Pharmacy.

Arrest Made in Berlin Pharmacy Robbery

Berlin police have arrested Jesse Pinkham, 26, in connection with a robbery of the Berlin Walmart pharmacy in early December. Police say Pinkham handed the pharmacist a note threatening to use a weapon if he did not get what he wanted. Pinkham was charged with assault, robbery, and possession of narcotics, and was held on bail.

Save the Date: Vermont Legislative Day

Vermont Pharmacists Day will be held on January 22nd at the Statehouse in Montpelier.

VPA Spring Meeting Date

The Spring Continuing Education meeting will be held at the Holiday Inn in Rutland on Sunday April 3rd, 2016. The topic for this meeting will be on Opiates, and more information will be available in your mailboxes soon.

Upcoming Board of Pharmacy Meeting

The next meeting of the Board of Pharmacy will be held at 9 AM on January 27th. The meeting will be held on the 3rd floor of the City Center, 89 Main Street in Montpelier.

National Pharmacy News

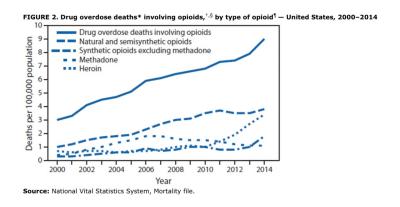
Naproxen Monotherapy Best For Reducing Acute Lower Back Pain

A recent double-blind randomized control trial found that acute back pain treated with naproxen alone resulted in similar efficacy when compared to naproxen plus oxycodone/acetaminophen or naproxen and cyclobenzaprine, with naproxen monotherapy associated with less adverse effects. The trial identified 323 adult patients aged 21 to 64 years, presenting to the emergency department with acute musculoskeletal lower back pain. Patients were excluded for the following reasons: pain that radiated below the gluteal folds, direct trauma to the back within the past month, pain for longer than 2 weeks, and recent history of lower back pain with more than 1 episode per month. Included patients were randomized to receive 500 mg naproxen twice daily for 10 days plus either placebo, 5 mg cyclobenzaprine, or 5-325 mg oxycodone/acetaminophen taken 1-2 tablets every 8 hours. Results of the intention-to-treat analysis found no significant differences in pain and function scores between the three treatment groups at follow up durations of 7 days and 3 months. Adverse effects including drowsiness, dizziness, dyspepsia, and nausea or vomiting were significantly increased in the oxycodone/acetaminophen and cyclobenzaprine treatment groups compared to the naproxen alone treatment group.

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Mortality from Opioid Overdose at Record High

Based on 2014 statistics released by the CDC in December, more people died from drug overdoses in the United States than during any



previous year on record, with an increase in deaths by 14% in 2014 compared to 2000 when data collection began. Opioid overdose deaths (including heroin) were responsible for 61% of all drug overdose deaths in 2014, representing a major reason for this record increase. Specifically, heroin-related deaths increased by 26%, deaths from natural and semi-synthetic opioids (such as morphine, oxycodone, and hydrocodone) increased by 9%, and synthetic opioid deaths spiked by 80% all compared to data from 2013. The synthetic opioid category included drugs like illicitly manufactured fentanyl and synthetic pain relievers such as tramadol, but does not include methadone. The CDC recommends expanding access to naloxone and opioid addiction treatment, and encourages safer prescribing of opioid pain relievers to help address this drastic increase in opioid-related deaths.

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Novo Nordisk and IBM Watson Health Partner for Diabetes Patient Management

To help patients manage their diabetes, Novo Nordisk and IBM Watson Health have partnered to use the Watson Health Cloud technology to help patients better manage their health. The companies will research possibilities in improving diabetes care through analysis of health data, with the aim of creating a virtual doctor to aid patients in providing diabetes management advice, such as insulin dosage. Blood sugar monitor data, food intake, and information on insulin dosage and timing could also be analyzed using the Watson Health technology.

Generic Lantus Release Set for December 2016

The FDA approved Basaglar (insulin glargine, Eli Lilly) for use in adults and children with type 1 and adults with type 2 diabetes, making this the first approval of an insulin product through the FDA's 505(b)(2) regulatory pathway. The approval of this biosimilar to Lantus comes after the product was awarded tentative approval in August 2014. Eli Lilly stated that Basaglar will be available in the US starting on December 15th, 2016. No price has been set for the drug, although a spokesperson for the company stated it would be cheaper than Lantus.

FDA Strengthens Oversight of Dietary Supplements

The FDA has announced the creation of a new office to help better regulate the growing dietary supplement industry. The Office of Dietary Supplement Programs (ODSP), which was previously a division under the FDA's Office of Nutrition and Labeling and Dietary Supplements, will be responsible for removing dangerous supplements from the market and acting on claims in cases involving harm to consumers or economic fraud. The ODSP will also be responsible for removing products with false labeling from the market and ensuring consumer safety. The FDA is currently in the process of identifying leadership for this new office

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Study Finds Liraglutide Safe in Patients with Renal Failure

The LIRA-RENAL trial funded by Novo Nordisk studied the use of Victoza in patients with type 2 diabetes and moderate renal impairment. In data published online in the journal *Diabetes Care*, results from this study involving patients with type 2 diabetes and eGFR between 30-59 mL/min confirmed that liraglutide added-on to insulin or other oral diabetes medications lowered HbA1c from baseline relative to placebo and did not result in worsening of renal function in patients over the 6-month study period. Patients taking liraglutide also experienced weight loss, a known advantage of GLP-1 agonists. Gastrointestinal side effects, such as nausea and vomiting, were higher in patients receiving liraglutide compared to placebo (35.7% vs. 17.5%) and the liraglutide treatment group also had a higher withdrawal rate due to side effects than the placebo group (13.6% vs. 2.9%).

Warfarin and Sulfonylurea Combination Associated with Higher Hypoglycemia Risk in Retrospective Study

The use of warfarin in combination with glipizide or glimepiride increased risk for severe hypoglycemia in older adults according to results of a study published in the BMJ. The study retrospectively analyzed information by using a random sample of over 12 million adults aged 65 years and older from the Medicare database. Of these patients, 465,918 had type 2 diabetes and filled at least one prescription for glipizide or glimepiride; 15.4% of these patients also filled a prescription for warfarin during the study period of 2006 to 2011. The retrospective analysis found an association between use of warfarin and glipizide or glimepiride with emergency-department visits and hospital admissions for hypoglycemia and fall-related fractures. Timing of these events was associated strongly with timing of starting warfarin in patients who were already on a sulfonylurea. The researchers also believe this study underestimated hypoglycemia risk, since most patients with hypoglycemia do not present to the emergency department and only three ICD-9 codes were used to identify hypoglycemia in their analysis. A drug-drug interaction is suspected to be the cause of increased risk of hypoglycemia, because no associations were seen for concurrent warfarin use and hypoglycemia risk with other diabetes medications or for concurrent use of sulfonylureas with statins. While some theories for this interaction include hepatic metabolism competition for CYP2C9 or displaced protein binding of the sulfonylurea by warfarin. no empiric evidence has been found to support a mechanism leading to varied reports of potential interaction in clinical databases. The authors highlight the important role MTM may play in monitoring older patients taking glipizide or glimepiride and warfarin, stating that the role of MTM in preventing hypoglycemia in these patients could result in important clinical benefits for Medicare beneficiaries and economic benefits through reducing hospitalizations.

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Drug-Drug Interaction Risks with New HCV Medications

Patients taking direct acting antivirals, such as boceprevir, teleprevir, and sofosbuvir, to treat hepatitis C infection are at risk of clinically significant drug-drug interactions that may potentially result in treatment failure. With insurance companies covering these medications, they will continue to be prescribed for HCV treatment. To study potential for clinically significant drug-drug interactions, researchers identified 261 HCV-infected patients taking a median of two other drugs with 20% of participants not taking any other medications. Researchers determined potential for drug-drug interactions between the patient's HCV treatment regimen and reported outpatient medications using http://www.hep-druginteractions.org and drug prescribing information. The most commonly used medications by participants were pantoprazole (18.8%), spironolactone (16.5%), levothyroxine (16.5%), and hydrochlorothiazide (10%). The HCV treatment associated with the highest risk of clinically significant drug interactions were the combination of medications included in Viekira Pak (ombitasvir/paritaprevir/ritonavir and dasabuvir), or ombitasvir/paritaprevir/ritonavir without dasabuvir. Patients taking these medications had a potential risk of serious drug-drug interactions of 66.3%. The lowest potential risk of interactions was associated with use of Sovaldi (sofosbuvir) plus ribavirin, with a potential risk of 9.6%. Other studied medications included Olysio (sofosbuvir/simeprevir), sofosbuvir/daclatasvir, and Harvoni (sofosbuvir/ledipasvir), which had a potential risk for drug-drug interactions of 31.4%, 36.8%, and 40.2% respectively. Researchers highlighted many prescribers are unaware of potential drugdrug interactions with new treatment regimens for HCV, and concluded a thorough evaluation of interactions is necessary to ensure patient safety and drug efficacy.

Contact Information:

Mailing Address:

Vermont Pharmacists Association P.O. Box 818 Milton, Vermont 05468

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