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A PHARMACY CONTINUING EDUCATION PROGRAM

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April 2012 "PART 1---NEW DRUGS OF 2011-2012"

THIS MONTH "New Drugs 2011-2012"

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DON'T FORGET CPE MONITOR. IT'S A REALITY NOW.

The FDA approved 35 new drugs in 2011. Of these we will specifically discuss eight that seem like they will have the biggest immediate impact on therapy. We'll present 3 in this lesson, and the remaining 5 in the next lesson. This lesson provides 1.25 hours (0.125 CEUs) of credit, and is intended for pharmacists in all practice settings. **The program ID # for this lesson is 707-000-12-004-H01-P. Pharmacists completing this lesson by April 30, 2015 may receive full credit.**

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

If you have any comments, suggestions or questions, contact us at the above address, or call toll free 1-800-323-4305. (In Alaska and Hawaii phone 1-847-945-8050). **Please write your ID Number (the number that is on the top of the mailing label) in the indicated space on the quiz page** (for continuous participants only).

The objectives of this lesson are such that upon completion the participant will be able to:

1. Describe the new drugs approved during 2011.
2. Discuss the role of these new drugs in therapy.
3. Summarize the new drugs' adverse effects & potential drug interactions.
4. Recommend counseling points associated with the new drugs.

INTRODUCTION

The Food and Drug Administration (FDA) approved 35 new chemical entities in 2011 compared to only 21 in the previous year.[1] In the past decade; only one other year saw such a high number of approvals. That was 2009 when there were 37 approvals. A number of clinical breakthrough agents were approved this past year, including 2 for hepatitis C, the first new agent for lupus in 50 years and 7 agents that are major advancements in cancer treatment. Almost 50% of these agents were given "priority" review, which accelerates the safety and efficacy review process to 6 months. A total of 10 agents were approved for rare or "orphan" diseases.

EIGHT OF THESE DRUGS WILL BE DISCUSSED IN THIS LESSON & IN NEXT MONTH'S. IN THIS LESSSON WE'LL DISCUSS THE 1ST 3 DRUGS. THE BALANCE WILL BE DISCUSSED IN PART 2 NEXT MONTH.

1. Ticagrelor (Brilinta™)—-a cardiovascular agent (antiplatelet agent); used to treat acute coronary syndrome.
2. Linagliptin (Tradjenta™)—-an endocrine drug (DPP-4 inhibitor); used to treat type 2 diabetes.
3. Rivaroxaban (Xarelto™)—-a cardiovascular agent (oral factor Xa inhibitor); used to treat atrial fibrillation & prophylaxis of DVT (deep vein thrombosis) in hip & knee surgery.

4 & 5. Telaprevir (Incivek™) & Boceprevir (Victrelis™)—-both are G.I. drugs (oral protease inhibitors); used for chronic hepatitis C.

6. Fidaxomicin (Dificid™)—-an infectious disease/immunology drug (macrolide antibiotic); used for *Clostridium difficile*-associated diarrhea.
7. Roflumilast (Daliresp™)—-a respiratory/pulmonary agent (oral phosphodiesterase type 4 inhibitor); used to reduce COPD exacerbations.
8. Indacaterol (Arcapta™)—-a respiratory/pulmonary agent (long-acting beta-agonist); used to treat COPD.

TICAGRELOR (BRILINTA™)

Ticagrelor is a platelet inhibitor and was approved by the FDA on July 24, 2011.[3,4] Ticagrelor offers some advantages over clopidogrel. When combined with 75 to 100 mg aspirin daily, ticagrelor was found to be superior to clopidrogel in preventing heart attacks and death. In addition, the elimination half-life of ticagrelor is much shorter than clopidogrel which can be a benefit in patients who are experiencing bleeding as an adverse event or who need to undergo surgery.

Pharmacology/Pharmacokinetics

Ticagrelor is the first agent in a new class of nonthienopyridine platelet inhibitors called cyclopentyltriazolopyrimidines.[3] Ticagrelor blocks the platelet $P2Y_{12}$ receptor to inhibit the prothrombotic effects of adenosine diphosphate (ADP). Ticagrelor does not require *in vivo* activation.

Ticagrelor is rapidly absorbed and has a rapid onset of platelet inhibition.[3,4] Peak inhibition of platelets occurs within 2 hours of oral administration. Ticagrelor is further metabolized by CYP3A4, to a major active metabolite. Metabolism occurs primarily through the liver, using CYP3A4 as the major enzyme for both ticagrelor and its active metabolite. Elimination is primarily through the feces, with less than 1% of the dose eliminated in urine. The active metabolite is most likely eliminated through biliary secretion. The elimination

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half-life is 7 hours for ticagrelor and 9 hours for its active metabolite. Ticagrelor is approximately 99% bound to plasma proteins.

Indications

Ticagrelor is approved for use in patients with acute coronary syndrome (ACS) to reduce the risk of cardiovascular events and myocardial infarction.[3] Maintenance doses of aspirin >100 mg decreased the effectiveness of ticagrelor. Maintenance doses of aspirin >100 mg daily should be avoided with this agent.

Dosing

The recommended dose of ticagrelor is a 180 mg oral loading dose followed by 90 mg twice daily as a maintenance dose.[3,4] Following an initial loading dose of aspirin, ticagrelor should be used with a maintenance dose of 75-100 mg aspirin once daily. Ticagrelor can be given without regard to meals. If switching from clopidogrel to ticagrelor, initiate ticagrelor 24 hours after the last clopidogrel dose.

Contraindications

Ticagrelor is contraindicated in patients with severe liver disease because of a risk of increased exposure of the drug.[3] It is also contraindicated in patients with a history of intracranial hemorrhage since this group is at high risk for recurrent intracranial bleed. It is also contraindicated in patients with active bleeding, such as those with an active intracranial hemorrhage or peptic ulcer disease.

Drug Interactions

Table 1. Common drug interactions with ticagrelor.[4]

Interacts with	Effect
Potent inducers of CYP3A (rifampin, dexamethasone, phenytoin, carbamazepine)	Reduced ticagrelor levels
Potent inhibitors of CYP3A (ketoconazole, itraconazole, clarithromycin, saquinavir, nelfinavir, indinavir, atazanavir, telithromycin)	Increased ticagrelor levels
Simvastatin, lovastatin	Increased simvastatin, lovastatin levels. Avoid statin doses > 40 mg.
Digoxin	Increased digoxin levels
Aspirin	Aspirin doses > 100 mg reduce efficacy of ticagrelor

Warnings

Do not stop ticagrelor, as this will increase the risk of cardiovascular events, including myocardial infarction, thrombosis and death.[3] If ticagrelor must be stopped temporarily for surgery or bleeding complications, it should be restarted as soon as possible.

Adverse Effects

The most common adverse effect reported with ticagrelor is bleeding.[3,4] Additional common adverse events (at least 3% occurrence) seen in clinical trials with ticagrelor include dyspnea, headache, cough, dizziness, nausea, atrial fibrillation, hypertension, non-cardiac chest pain, diarrhea, back pain, hypotension, fatigue, and chest pain. Ticagrelor has also been associated with bradycardia, gynecomastia, increased serum uric acid, and increased serum creatinine in comparison to clopidogrel.

Pregnancy and Lactation

Ticagrelor is classified as Pregnancy Category C by the FDA.[3] There are no well-controlled trials using ticagrelor in pregnant women. Its use should be reserved only when the benefit outweighs the risk. There is no data on the excretion of ticagrelor in human breastmilk. Use in breastfeeding women should be avoided unless the benefit outweighs the risk.

Counseling the patient

The pharmacist should counsel the patient to monitor for signs and symptoms of bleeding. Signs of bleeding would include black tarry stools, coffee-ground emesis, hemoptysis (expectoration of blood or blood-stained sputum), bleeding gums, or blood in the urine. The pharmacist should discuss potential drug interactions with ticagrelor and instruct the patient to avoid taking high doses of aspirin-containing products. Do not stop ticagrelor without talking to the prescribing physician. Discontinuation of ticagrelor increases the risk of cardiovascular events.

Role in therapy

Ticagrelor has been shown in clinical trials to be more effective than clopidogrel in reducing the composite of cardiovascular death, myocardial infarction, or stroke without a significant increase in major bleeding.[3] Ticagrelor does not require *in vivo* activation and has activity in clopidogrel nonresponders. In February 2012, the American College of Chest Physicians (ACCP) updated its guidelines on Antithrombotic Therapy and Prevention of Thrombosis to include a recommendation adding ticagrelor as an option with low-dose aspirin to patients who suffer from Acute Coronary Syndrome (ACS).[5]

LINAGLIPTIN (TRADJENTA™)

Linagliptin is the 3rd dipeptidyl peptidase-4 (DDP-4) inhibitor approved by the FDA.[6] It was approved on May 2, 2011. The other DDP-4 agents approved for use in the United States include saxagliptan (Onglyza™) and sitagliptin (Januvia™).[4]

Pharmacology/Pharmacokinetics

DPP4 inhibitors work by blocking DPP-4, an enzyme that breaks down gut peptides, especially glucagon-like peptide-1 (GLP-1).[4,6] GLP-1 slows glucose absorption from the gut, increases insulin secretion from the pancreas and lowers high levels of glucagon.

Linagliptin is well absorbed after oral administration.[6] Linagliptin is excreted primarily as unchanged drug, so metabolism is insignificant. The drug is excreted primarily via the feces. The elimination half-life of linagliptin is 12 hours allowing for once daily dosing.

Indications

Linagliptin is approved for use in combination with diet and exercise for the treatment of type 2 diabetes.[6]

Dosing

The dose of linagliptin is 5 mg once daily.[6] There is no dosage adjustment required for patients with renal or liver impairment. The drug can be administered without regard to meals.

Contraindications

Linagliptin is contraindicated in patients with a history of allergic reactions to the drug.[6]

Drug Interactions

The efficacy of linagliptin may be reduced when combined with rifampin; alternative therapy is recommended.[4,6] Ritonavir may increase linagliptin exposure, so this combination should be used with caution.

Warnings

There is an increased risk of hypoglycemia when linagliptin is combined with oral sulfonylureas.[6] The dose of the oral sulfonylureas may need to be reduced when adding linagliptin.

Adverse Effects

The DPP-4 inhibitors are a relatively safe class of agents to treat diabetes.[4,6] Unlike some diabetes medications, these agents are not associated with gastrointestinal side effects and are weight neutral. Their risk of hypoglycemia is similar to that of metformin, and is less than that of the sulfonylureas. When combined with an oral sulfonylurea, patients have reported hypoglycemia. The primary adverse effects reported with linagliptin include nasopharyingitis (> 5%), headache, arthralgia and cough.

Pregnancy and Lactation

Linagliptin is pregnancy category B.[6] There are no well-controlled trials in pregnant women, although the drug does cross the placenta in pregnant rabbits and rats. It should only be used in pregnancy if the risk outweighs the benefits. It is not known if linagliptin is excreted into human milk. It should be used with caution in breastfeeding women.

Counseling the patient

The pharmacist should discuss the importance of adherence to linagliptin with the patient. Discuss the overall management of diabetes including the need to test blood sugar and adherence to the proper diet and exercise. It is important for the pharmacist to review the signs and symptoms of hypoglycemia and hyperglycemia when a patient is started on linagliptin. Be sure to ask the patient to explain back to you how they intend to take the medication so that you can be sure they understood your instructions. Make a point of reinforcing the information when the patient returns for refills of their prescription.

Role in therapy

There is no data to suggest that one DPP-4 inhibitor is superior to another.[7,8] All 3 of the DPP-4 inhibitors have been shown to reduce A1C in comparison to placebo. The greatest reduction in A1C and other glycemic parameters is seen when a DPP-4 inhibitor is used in combination with another agent as dual therapy. As dual therapy, the combination of a DPP-4 inhibitor and metformin is similar in efficacy to a sulfonylurea and metformin, without a greater risk for hypoglycemia. The DPP-4 inhibitors are weight-neutral and in some instances, result in weight loss compared to placebo. In comparison to other antihyperglycemic agents, DPP-4 inhibitors have a relatively mild adverse effect profile and a low risk of drug-drug interactions.

RIVAROXABAN (XARELTO™)

Rivaroxaban is the first orally bioavailable, selective, factor Xa inhibitor to be approved by the FDA.[9] Rivaroxaban is the 2nd new oral anticoagulant approved in the last 2 years. Dabigatran (Pradaxa™), a thrombin inhibitor, was approved by the FDA in October 2010.[4] Both dabigatran and rivaroxaban have been approved as alternatives to warfarin in nonvalvular atrial fibrillation.

Pharmacology/Pharmacokinetics

Rivaroxaban provides anticoagulation by selective inhibition of factor Xa without the need of a cofactor such as anti-thrombin III for activity.[4,9,10] Rivaroxaban is well absorbed following oral administration. It has

an elimination half-life of 5 to 9 hours, which is extended to 11 to13 hours in the elderly. Rivaroxaban is highly plasma protein bound (92 to 95%) and is metabolized by CYP3A4, 3A5, and 2J2. It is eliminated both in the urine (66%) and feces (28%).

Indications

Rivaroxaban is approved to reduce the risk of stroke or embolism in patients with nonvalvular atrial fibrillation.[9] It also is approved for prophylaxis of deep vein thrombosis (DVT) in patients undergoing hip and knee replacement.

Dosing

Table 2. Nonvalvular Atrial Fibrillation[9]

Creatinine Clearance (CrCl)	Dose
> 50 mL/min	20 mg once daily with evening meal
15 to 50 mL/min	15 mg once daily with evening meal
< 15 mL/min	Avoid use

Switching patient from warfarin:[9]

Discontinue warfarin and begin rivaroxaban when the International Normalized Ratio (INR) is below 3.0.

Switching patient from anticoagulant other than warfarin: Administer rivaroxaban 0 to 2 hours before the evening dose of the anticoagulant (e.g. low molecular weight heparin) and discontinue the other anticoagulant.

If converting from heparin infusion, begin rivaroxaban and discontinue heparin at the same time.

DVT Prophylaxis[9]

Start rivaroxaban 10 mg once daily. Begin treatment 6 to 10 hours after surgery. Patients undergoing knee replacement surgery should be treated for 12 days, while patients having hip surgery should continue for 35 days. Do not administer rivaroxaban prophylaxis to patients with a CrCl < 30 mL/min and use with caution in patients with CrCl of 30 to 50 mL/min.

Contraindications

Do not administer if the patient is allergic to rivaroxaban or if there is active bleeding (e.g. peptic ulcer, intracranial hemorrhage).[9,10]

Drug Interactions

Table 3: Common drug interactions with rivaroxaban[4,9,10]

Interacting drug class	Drugs		Effect
Inhibitors of CYP3A4 enzymes and drug transport systems	ketoconazole clarithromycin	ritonavir erythromycin	Significant increase in rivaroxaban exposure
Inducers of CYP3A4 enzymes and drug transport systems	rifampicin phenytoin	carbamazepine St. Johns Wort	Significant decrease in rivaroxaban exposure
Anticoagulants	warfarin		Increased risk of bleeding
Platelet Inhibitor	clopidogrel		Increased risk of bleeding
NSAIDs/Aspirin	ibuprofen aspirin		Increased risk of bleeding

NSAIDS=non-steroidal anti-inflammatory drugs.

Warnings

Discontinuation in patients with nonvalvular atrial fibrillation[9]

Rivaroxaban should not be discontinued in patients with atrial fibrillation due to increased risk of thrombotic events.

Spinal/Epidural anesthesia or puncture

Rivaroxaban increases the risk of developing an epidural or spinal hematoma, which can result in long-term or permanent paralysis.

Adverse Effects

The most serious adverse effect with rivaroxaban is bleeding, including fatal bleeding.[9,10] Other adverse effects include muscle pain and spasm, syncope, pruritis, agranulocytosis and Stevens Johnson Syndrome.

Pregnancy and Lactation

Rivaroxaban is considered pregnancy category C.[9] Use in pregnant women has been associated with pregnancy-related hemorrhage and emergent delivery. It is unknown if rivaroxaban is excreted in human milk. It should only be used by nursing mothers when the benefit outweighs the risk.

Counseling the patient

The pharmacist should discuss the importance of adherence to rivaroxaban. Discuss the risk of developing an embolism if the medication is discontinued without medical supervision. Remind patients to tell the dentist or physician that they are taking rivaroxaban prior to any dental or invasive procedure. Patients should be counseled to avoid taking any other prescription, non-prescription or herbal products without first talking to a healthcare professional. As with other anticoagulants, patients taking rivaroxaban should be counseled about the importance of compliance with this regimen to prevent potentially life-threatening thrombus or stroke.

Role in therapy

Rivaroxaban provides another alternative to warfarin in nonvalvular atrial fibrillation.[9,10] Rivaroxaban has been shown to be effective in preventing stroke and systemic embolism in this patient population. Rivaroxaban does not have the drug or dietary interactions seen with warfarin and does not require laboratory monitoring.

Rivaroxaban cannot be used in patients with renal failure. It may offer an advantage in patients who are intolerant or non-compliant with warfarin.

Rivaroxaban is administered once daily compared to dabigatran which is given twice daily.

CASE SCENARIO

A physician calls your pharmacy to ask about prescribing rivaroxaban to a patient who has not been well-controlled on warfarin because they will not return for lab testing as instructed. The physician is concerned because he is not sure how to convert the patient from warfarin to rivaroxaban. What do you tell him in order to assist in the conversion?

You explain to the physician that the warfarin dose is stopped and rivaroxaban is started when the INR is less than 3. You explain that the initial starting dose of rivaroxaban is 20 mg once daily with the evening meal. If the patient has a CrCl of 15 to 50 mL/minute the dose should be reduced to 15 mg once daily (with the evening meal). Patients with a CrCl <15 mL/min should avoid using rivaroxaban.

The doctor states that the patient's INR is currently 2.8 and his renal function is 72 mL/min. The patient leaves the physician office and stops at your pharmacy to have the prescription for rivaroxaban filled. What specific information do you provide to the patient when counseling him?

You explain to the patient that rivaroxaban is a new medication that the doctor is prescribing to replace the warfarin (Coumadin™) prescription. You explain that the patient should not take the warfarin any longer. You explain that the rivaroxaban is taken once a day. You ask the patient if they understand why they are taking the medication. The patient states that this medication is supposed to thin the blood and prevent a blood clot or a stroke. You reinforce the importance of taking this medication each day with the evening meal. You reinforce that the INR blood test required with warfarin is not needed with the new medication. You counsel the patient to avoid NSAIDs and other drugs that may increase the risk of bleeding. After you answer any additional questions the patient may have, you ask them to explain to you how they will be taking this medication.

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ANTICIPATED TOPICS FOR BALANCE OF 2012

New drugs 2011-2012-Part 2	Cholesterol management
ADHD	*C diff.*
Update: nuclear pharmacy	Nosocomial infections
Healthcare impact on pharmacy	

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LESSON EVALUATION

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?

Describe new drugs that were approved in 2011	Yes	No
Discuss roles of the new drugs in therapy	Yes	No
Summarize the adverse effects & drug interactions associated with the new drugs	Yes	No
Recommend counseling points that should be associated with the new drugs	Yes	No

2. Was the program independent & non-commercial Yes No

	Poor			Average		Excellent	
3. Relevance of topic	1	2	3	4	5	6	7

4. What did you like most about this lesson?_____

5. What did you like least about this lesson?_____

Please Select the Most Correct Answer(s)

1. When converting a patient from warfarin, before starting rivaroxaban, the INR should be below:
   A. 2.5
   B. 3.0
   C. 1.5
   D. 1.0
2. Ticagrelor should be taken with what dose of aspirin?
   A. 75 to 100mg
   B. 325mg
   C.> 100mg
   D. 650 mg
3. Metabolism of linagliptin is a significant issue.
   A. True B. False
4. The dose of rivaroxaban for DVT prophylaxis is:
   A. 10mg once daily
   B. 15mg once daily
   C. 20mg once daily
   D. 30mg once daily
5. Ticagrelor combined with aspirin was found superior to _____ in preventing heart attacks.
   A. Clopidogrel
   B. Coumadin
   C. Pradaxa™
   D. Indacaterol
6. Metabolism of ticagrelor occurs primarily in:
   A. Bile ducts
   B. Small intestine
   C. Kidney
   D. Liver
7. Ticagrelor should not be used in patients with:
   A. Kidney failure
   B. PUD
   C. Severe liver disease
   D. COPD
8. Linagliptin is a(an):
   A. Oral sulfonylurea
   B. DPP-4 inhibitor
   C. Incretin mimetic
   D. None of these
9. Using an oral sulfonylurea with linagliptin increases risk of:
   A. Skin rash
   B. Hypoglycemia
   C. Hyperglycemia
   D. Hypertension
10. The most severe adverse effect with rivaroxaban is:
    A. Diarrhea
    B. Vomiting
    C. Bleeding
    D. Joint pain

Contributing Author
Mary Lynn Moody, BS Pharm
Clinical Assistant Professor
Director, Business Development
Drug Information Group
University of Illinois, Chicago
College of Pharmacy

Executive Editor
William J. Feinberg,
BS Pharm, MBA

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