



LA HEALTH-SYSTEM PHARMACIST

Newsletter of the Louisiana Society of Health-System Pharmacists

Editor: Dana Jamero djamero@xula.edu

www.lshp.org

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FROM THE DESK OF THE PRESIDENT

A year has almost passed and my time as LSHP President is quickly coming to an end. I feel as though it was just yesterday when I was sworn in at the Hilton. I have enjoyed serving the members of LSHP and representing our state at the meetings that I've attended on behalf of the organization.

I wanted to move away from the typical column and show my gratitude to the large group of people who have made the past year a success. I want to start by thanking Kati Craig and Bland O'Connor from the LSHP main office. They have done a great job of assisting me with everything imaginable over the past year. They both have the patience of a saint. Second, I wanted to thank the:

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Finally, I want to thank you, the members, of our organization. Without your membership and support the past year would have not gone so well. I also wanted to encourage you to get involved with LSHP on the local or state level.

The LSHP Annual Meeting is quickly approaching and will be held on May 26-28, 2011 in New Orleans at the Hilton Riverside. We have a very exciting program in store for our members. Education sessions will begin Thursday afternoon followed by the Welcome Reception at Rock & Bowl in the evening. On Friday the meeting will have a full day of educational sessions, poster presentations, and the exhibits. Saturday will be the last day of the meeting with continuing education, the LSHP Annual Awards luncheon, and the presentation of the LSHP Annual Awards. For further information, please see the LSHP website for the meeting brochure and for online registration. I look forward to seeing you all at the meeting.

Sincerely,
Teresa Nash
LSHP President



Welcome to the following members who joined LSHP since January of 2011!

John Edward Broussard, RPh	LaKeisha George Williams, PharmD
Rachel A. Triche, CPhT	Kim Harvey, RPh
Erin Crisson, PharmD	Julie Chimeno, PharmD
Sarah Amering, PharmD	Taylor Miller, CPhT
Lori Crawford, PharmD	Tina Tweedley, PharmD
Cindy Duet	



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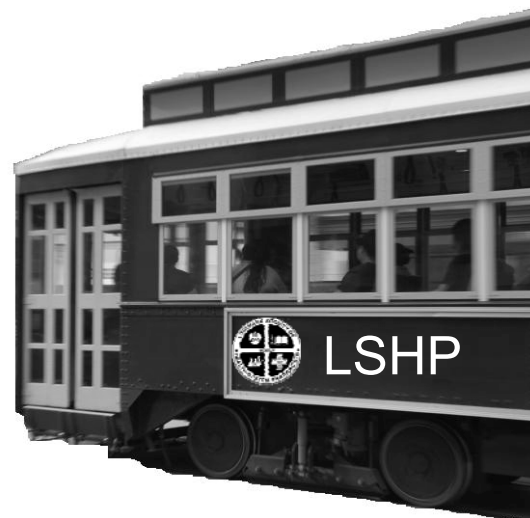
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Save the date &
hop on board!

**LSHP 2011
Annual Meeting**

May 26-28, 2011
Hilton Riverside

Hotel room reservations may be made by calling the Hilton at (504) 561-0500 or 1-800-HILTONS. Rooms are \$199. Rooms must be booked by April 23 to be included in the LSHP room block. When you reserve your room, please tell them that you are in the LSHP room block and use the group code, "LSH."

**LSHP Bimonthly Newsletter****LA HEALTH-SYSTEM PHARMACIST****Publisher Information**

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Copy, advertising and nonmember subscription inquiries should be directed to the Copy Editor, Kati Craig, at (225) 922-4520. Advertising rate sheets and deadlines are available upon request.

Please send article submissions to the newsletter editor, Dana Jamero, via email at djamero@xula.edu.

Schedule of Activities at the LSHP 2011 Annual Meeting

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2:00-2:15 p.m. Welcome & Announcements

2:15-3:15 p.m.

Hemostasis in the Surgical Patient: Getting Out of the Pharmacy Silo

3:15-4:15 p.m.

HIV in 2011: Where Are We At and Where Are We Going?

4:15-5:15 p.m.

Not for Your Bath, Your Plants and Especially Not for You. The Latest Designer Drugs of Abuse.

5:15-6:15 p.m.

Education Session Title to be determined

7:00-9:30 p.m.

LSHP Welcome Reception- Rock & Bowl

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8:00-9:30 a.m.

A Pharmacist's Roadmap to Pain Management: New Directions to Improved Patient Care

9:45-10:45 a.m.

ESA Risk Evaluation and Mitigation Strategies: ESA APPRISE Program Overview

11:00 a.m.– 12:00 p.m.

Enhancing Patient Safety Through USP <797> Compliance

12:00-3:00 p.m.

Lunch/Exhibits/ Poster Session

3:00-4:30 p.m.

2011 Update on System Variations in the Delivery of Care for Multiple Myeloma

4:30-5:30 p.m.

Management of Symptoms Near the End of Life

5:30-6:30 p.m.

Emerging Threat of Multidrug Resistant Organisms

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8:00-9:00 a.m.

Investigating Stroke Treatment: Bedside to Bench and Back

9:00-10:00 a.m.

Top 10 Gaps in USP 797 Compliance

10:00-11:00 a.m.

Radiology Procedures & Contrast Agents

11:00 a.m.-12:00 p.m.

General Membership Meeting

12:00-2:00 p.m.

Awards Luncheon and Featured Presentation, "Pharmacy Practice Model Initiative"

2:00-3:00 p.m.

Drug Policy Trends and Controversies 2011

Visit www.lshp.org for more information, to download a brochure with registration form, or to register online!

The Newest ARB: Edarbi™

By: Shrouq Qaisi, PharmD Candidate and Jamie Terrell, PharmD

Hypertension, also known as the “silent killer”, is a prominent problem in the United States. Roughly one out of three American adults has high blood pressure and 22.4% of those affected are unaware of their hypertensive status. Hypertension is a risk factor for stroke, congestive heart failure, and kidney disease, which is why control of this disease is imperative. Despite therapeutic advances, more than 50% of patients who take antihypertensive drugs still have uncontrolled blood pressure.¹ There are many drug classes to choose from for the primary treatment of hypertension, such as diuretics, angiotensin receptor blocker (ARBs), angiotensin converting enzyme inhibitors (ACEI), and calcium channel blockers (CCB). On February 25, 2011, the FDA approved azilsartan medoxomil for the treatment of hypertension. This new ARB is promising; it was shown to be more effective than two other ARBs for patients with hypertension.²

Azilsartan medoxomil is manufactured through Takeda and marketed under the name Edarbi®. It is a prodrug that is hydrolyzed into the active metabolite, azilsartan, in the gastrointestinal tract. Azilsartan binds to the AT1 receptors thus preventing angiotensin II from binding to the AT1 receptors, and indirectly inhibiting the actions of angiotensin II. Angiotensin II is a vasopressor hormone that leads to vasoconstriction, aldosterone production, and renal absorption of sodium, all of which can increase a patient's blood pressure. Azilsartan is available in a 40mg and 80mg tablet. The recommended dose is 80mg; however, the 40mg dose can be used in patients who are on a high dose of a diuretic. The most common adverse effects are comparable to those of other ARBs and include dizziness, diarrhea, and increased blood creatine phosphokinase. There have been no reported noteworthy drug interactions except the possibility of worsening renal function with NSAID use in elderly patients, those with impaired renal function, or volume depleted patients. In these patients renal function should be monitored. Azilsartan is also similar to other ARBs in that it should not be used in pregnant patients.³

Azilsartan has demonstrated high potency in several studies when compared to other antihypertensive agents. Azilsartan was compared to olmesartan in a phase III, double-

blind, randomized clinical trial.³ The study compared the mean systolic blood pressure lowering capacities of azilsartan 20mg, 40mg, and 80 mg; olmesartan 80mg; and placebo using ambulatory blood pressure monitoring for a 24 hour period. Blood pressure reductions at the end of the six week period were -12.2mmHg, -13.5mmHg, -14.6mmHg, and -12.6 mmHg for azilsartan 20mg, 40mg, 80mg, and olmesartan 40mg respectively. Azilsartan 80mg showed a significant superiority in systolic blood pressure reduction compared to olmesartan 40mg; while azilsartan 40mg showed non-inferiority when compared to olmesartan 40mg. This implies that azilsartan 80mg is more potent than the highest dose of olmesartan. This can be attributed to the fact that azilsartan dissociates slower from the AT1 receptor when compared to olmesartan.²

In another placebo controlled, randomized, double blind, 6 week clinical trial, azilsartan 40mg and 80mg was compared to valsartan 320mg and olmesartan 40mg.⁴ Azilsartan 80mg (-14.3mmHg) demonstrated greater 24 hour mean systolic blood pressure reduction when compared to both valsartan (-10mmHg) and olmesartan (-11.7 mmHg). Moreover, both doses of azilsartan were superior in clinical systolic blood pressure reduction compared to valsartan and olmesartan.⁴

Azilsartan use could possibly lead to higher rates of blood pressure control. It has demonstrated superiority in reducing clinic and ambulatory blood pressure when compared to other ARBs. It is efficacious and well-tolerated, which increases the chance of patient compliance. Moreover, some animal studies suggest that azilsartan could have potential cardio-protective and anti-diabetic properties. In the adipose tissue of mice, azilsartan suppressed the production of TNF- α . It is believed that decreasing TNF- α production improves insulin resistance. Furthermore, the same study showed that azilsartan increased adiponectin, which decreases atherosclerotic changes. The researchers concluded that azilsartan could potentially play a role in patients with metabolic syndrome.⁵ These properties make azilsartan a desirable antihypertensive drug.

References available upon request.

SWLSHP Chapter Update

By: Ty J. Ledet, RPh, MSHSA
SWLSHP Chapter President

Ty Ledet, RPh and Heart Hospital of Lafayette Director of Pharmacy was sworn-in as the new president of the SWLSHP. There is much interest in the region to revitalize the chapter. A meeting of core members was held on March 1, 2011 in Lafayette to discuss the process of re-activating the chapter. The members present reviewed the only bylaws found, dated November 13,

1980. Suggestions to the bylaws were sent to the board of LSHP for review. The chapter is currently planning for its first meeting with all current active members of LSHP in an effort to spark interest in all areas of Health-Systems Pharmacy (hospitals, retail, infusion companies, nuclear etc).

Public Policy Update

By: William R. Kirchain, PharmD & Jeffery Evans, PharmD

On the eve of our legislature's annual adventure into law making, the biggest issue to no one's surprise is going to be about not having enough money to fund the government. We are expecting large fights over reductions in spending which will likely impact health care in Louisiana at all levels. Medicaid cuts will likely be the headliners, but deep cuts in other health related government agencies are likely and may have broader, more significant impact.

The first day of the Regular Session is Monday, April 25th. Along with the expected and predictable there will likely include proposals to "save" money for the state through schemes to repurpose, recycle and reuse medications which will most likely not be beneficial to anyone. The National Conference of State Legislators lists the following issues as significant for this year:

(1) This is the year that the underlying state regulations and rules for the state-based health insurance exchanges are to be established under the Affordable Care Act. Several governors are looking to use this as leverage with the Department of Health and Human Services in Washington to command changes in Medicaid rules.

(2) This is the year that the underlying state regulations and rules for compliance with the Affordable Care Act's Fraud, Waste and

Abuse rules. Included are requirements for expanded contracts for recovery audits and program integrity activities.

(3) Increasing either funding for or eliminating barriers to the creation of Medical Homes. The model that seems to be emerging for what a Medical Home should be is the federally qualified health center a.k.a. Community Health Centers.

In Louisiana, the Board of Pharmacy has posted two interesting new regulatory proposals. One attempts to define cognitive services and the second adds a requirement to the definition of PIC (Pharmacist in Charge). Proposal 2011-2 ~ Cognitive Services Draft No. 4 would add a new section (§525. Cognitive Services) to Chapter 5 of Title 46. Amongst other elements of the definition, our work on committees is included as a defined part of cognitive service. In addition, the proposal spells out that cognitive services provided outside a permitted pharmacy cannot include dispensing of medications. Regulatory Proposal 2011-1 ~ PIC Requirements adds the following statement to the general qualifications of all Pharmacists-in-charge; "The PIC shall be present and practicing at the pharmacy for which he holds the PIC position no less than 20 hours per week during the pharmacy's ordinary course of business." Additionally, the update requires that a PIC be licensed and practicing as a pharmacist for at least two years

Policy continued on page 8.

Position Open: Director of Pharmacy Natchitoches, LA



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ACE-I, ARBs, or Both?

By: Matthew Fitzgerald, PharmD Candidate & Teresa Nash, PharmD, BCPS

Angiotensin-converting enzyme inhibitors (ACE-I) and angiotensin receptor blockers (ARBs) have been used in the treatment of heart failure and hypertension. There are multiple studies that use the combination of ACE-I and an ARB to see if any benefit would occur with the combination. The combination of these products has been studied in multiple disease states including: heart failure, hypertension, diabetes, and proteinuria. The combination appears to have an added benefit; however, these benefits vary from disease state.

Heart Failure

The combination of ACE-I and ARBs has been used in multiple studies involving heart failure patients. The Valsartan Heart Failure Trial was a study that used valsartan in addition to other baseline therapy. Five thousand and ten (5010) patients were involved in the study; 92% of the patients were already using an ACE-I¹. The study found that using triple therapy (ARB, ACE-I, and beta-blocker) had an increase in mortality. However, adding valsartan to a patient taking an ACE-I without a beta-blocker showed improvement in morbidity although no change in mortality. The Candesartan in Heart Failure Assessment of Reduction in Mortality and Morbidity Trial (CHARM) found similar results². In the CHARM trial, candesartan was added to patients already taking heart failure medication. The study found that patients had a decrease in morbidity; however, the study also noted no change in mortality.

Hypertension

The use of ACE-I in combination with ARBs has not been extensively studied for the use in patients with hypertension with only small studies evaluating use in this indication. One study was conducted using a meta-analysis of trials from multiple databases³. In this study, patients receiving the combination of an ACE-I and an ARB had ambulatory blood pressure decrease by 4.7/3.0 mmHg. Patients receiving ACE-I monotherapy had blood pressure decrease by 3.8/2.7 mmHg and patients receiving ARB monotherapy had blood pressure decrease by 3.7/2.3 mmHg. The study noted that none of the studies were of sufficient size or duration to determine safety concerns. The study concluded that there is a small additive effect; however, the use of both ACE-I and ARBs in combination is not recommended until more controlled studies are performed.

Diabetes

The use of ACE-I and ARBs in combination was studied in the candesartan and lisinopril microalbuminuria (CALM) study⁴. The study assessed the effects of candesartan or lisinopril as single agents or in combination in patients with hypertension, microalbuminuria, and non-insulin dependent diabetes. The study noted a significant decrease in diastolic blood pressure with the use of combination therapy as well as a greater decrease in urinary albumin:creatinine ratio. The study concluded that candesartan was as effective as lisinopril in reducing blood pressure and microalbuminuria in hypertensive patients with type 2 diabetes.

Proteinuria

ACE-I and ARBs have been studied for their use in reduction of proteinuria; multiple studies have found that the combination of an ACE-I and an ARB will produce a greater reduction than individual agents. In a recent study, 156 patients received ACE-I and ARBs and 159 received ACE-I only⁵. The results of this study suggested that short-term combination therapy was superior to ACE-I in reducing 24-h urinary protein excretion in patients. The study speculated that the decrease may have occurred due to the diminished renal perfusion. The COOPERATE study determined that the combination of losartan and trandolapril resulted in a 50% reduction of the rate of doubling of serum creatinine or development of end-stage renal disease over a 3 year period⁶. The ONTARGET study also noted a decrease in proteinuria with combination therapy; however, the study suggested that the combination had overall worsening effects on renal outcomes⁷.

Conclusion

ACE-I and ARBs combination therapy can be used in a variety of disease states; however, the benefit of combination therapy depends on the disease state. In heart failure, studies have shown no change in mortality with combination therapy; however, morbidity in these studies was shown to have decreased. Combination therapy could be a viable option in heart failure due to the decrease in morbidity. In hypertension, combination therapy showed that blood pressure would decrease more than either agent alone; however, the safety profile was not monitored. Combination therapy for the treatment of hypertension should only be used in an institutional setting to monitor for renal function until more studies are completed to evaluate safety profile. For patients with type 2 diabetes with microalbuminuria and hypertension, combination therapy seems to be a possible option. Combination therapy was noted to have a greater decrease in urinary albumin:creatinine ratio compared to single agents. The use of combination therapy for the treatment of proteinuria varies based on the study. Combination therapy does produce a greater reduction than single agents; however, the ONTARGET study suggests that the combination will have an overall worsening of renal outcomes. With these varying results, more studies must be done to see if combination therapy has any effect on improving renal outcomes in patients with renal disease. The use of ACE-I and ARBs in combination could be a possible option for patients with heart failure, hypertension, or patients with type 2 diabetes with microalbuminuria and hypertension; however, the drug safety profile has not been established. The use of ACE-I and ARBs should only be used in institutional settings where patients are monitored for renal function frequently.

References:

1. Cohn JN, Tognoni G, Valsartan Heart Failure Trial Investigators. A randomized trial of the angiotensin-receptor blocker valsartan in chronic heart failure. *N Engl J Med* 2001; 345:1667-1675.

References continued on page 8.

Dabigatran for Stroke Prevention

By: Asia K. Scott, PharmD Candidate; Tibb Jacobs, PharmD

Atrial fibrillation affects more than 2 million people in the United States alone¹ and involves uncoordinated contractions of the atria which may lead to an irregular heart rate or rhythm. Blood is pooled due to these uncoordinated contractions, increasing the potential for clot formation and risk of stroke. Anticoagulation is the current therapy for stroke prevention in this case.

The current standard for anticoagulation therapy is warfarin sodium, a vitamin K antagonist. While warfarin has proven efficacious, the high bleeding risk, many drug interactions, and frequent monitoring often make it a less desirable choice for patients. Dabigatran etexilate (Pradaxa©) may prove to be an alternative to warfarin. In October of 2010, the FDA approved dabigatran's use for the prevention of strokes and blood clots in patients with abnormal heart rhythms¹.

Dabigatran etexilate is an oral thrombin inhibitor that has been shown to reversibly inhibit both thrombin generation and activity. Studies have shown that dabigatran exhibits predictable pharmacokinetics which allows for its fixed dose regimen. Because of this predictable profile, there is no need for coagulation monitoring. Dabigatran is only about 35% protein bound and is not metabolized by the cytochrome P450 isoenzymes which contribute to its very limited drug-drug interactions². Dabigatran is available in 75 mg and 150 mg capsules and is to be taken twice daily³.

The RE-LY trial⁴ was designed to compare two fixed doses of dabigatran etexilate with warfarin in patients with atrial fibrillation that were at an increased risk of stroke. Patients were recruited from 951 clinical centers in 44 countries and were eligible if they had documented atrial fibrillation by echocardiography at screening or within 6 months beforehand. Dabigatran was administered in a blinded fashion in either 110 mg or 150 mg doses taken twice daily and warfarin was administered in an unblinded manner in tablets of 1, 3, or 5 mg and was adjusted to an international normalized ratio (INR) of 2.0 to 3.0. The primary outcome for the study was stroke or systemic embolism. After two years, results showed that systemic embolism or stroke occurred in 182 (1.53% per year) patients receiving 110 mg of dabigatran, 134 (1.11% per year) patients receiving 150 mg, and 199 (1.69% per year) patients receiving warfarin. Rates of hemorrhagic stroke were 0.10% per year in the group receiving 150 mg of dabigatran, 0.12% per year in the 110 mg group, and 0.38% per year in the warfarin

group. Rates of myocardial infarction were higher in the dabigatran groups as compared with warfarin, and rates of major bleeding were higher with warfarin as compared with the dabigatran groups. Overall both dabigatran doses proved noninferior to warfarin ($p < 0.001$). A similar study⁵ comparing dabigatran's effect on venous thromboembolisms showed similar bleeding rates, increased incidences of dyspepsia, and overall noninferiority to warfarin.

Based on the study discussed, dabigatran is a realistic alternative to warfarin for anticoagulation therapy. In atrial fibrillation dabigatran provides equal efficacy with a better safety profile and ease of use. The majority of dabigatran is excreted renally and adjustments are necessary for impaired renal function. Patients should be counseled to watch for serious side effects such as chest pain or tightness, swelling of the tongue or throat, and trouble breathing or wheezing. Dabigatran also has several gastrointestinal side effects such as nausea, bloating, heartburn, and the dyspepsia mentioned above as well as increased rates of gastrointestinal bleeding^{1,3}. One of the most important factors of efficacy is patient compliance. With dabigatran's lack of monitoring and need for frequent adjustment, patients may be more inclined to be compliant with this medication as compared with warfarin.

References

1. FDA approves pradaxa to treat stroke in people with atrial fibrillation. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm230241.htm> . Accessed December 14, 2010.
2. Stangier J and Clemens A. Pharmacology, Pharmacokinetics, Pharmacodynamics of Dabigatran Etexilate, and Oral Direct Thrombin Inhibitor. *Clin Appl Thromb Hemos* 2009;15:9S-16S.
3. Pradaxa prescribing information. www.pradaxa.com. Accessed December 14, 2010.
4. Connolly SJ, Ezekowitz MD, Yusuf S, et al. Dabigatran versus Warfarin in Patients with Atrial Fibrillation. *N Engl J Med* 2009;361:1139-1151.
5. Schulman S, Kearon C, Kakkar AK, et al. Dabigatran versus Warfarin in the Treatment of Acute Venous Thromboembolism. *N Engl J Med* 2009;361:2342-2352.

PTCB Sponsored CE for Pharmacists & Pharmacy Technicians

Advancing the Pharmacy Team: Innovative Roles for PTCB Certified Pharmacy Technicians

This free PTCB sponsored Continuing Education (CE) is designed to meet the needs of pharmacy technicians and pharmacists interested in learning more about expanding roles, training, certification, and evolution of pharmacy technicians. Specifically, the program describes innovative opportunities for CPhTs to assist the health-system pharmacy team; discusses how pharmacists may be redeployed for clinical activities by utilizing CPhTs; describes the importance of including pharmacy technicians in medication safety, quality assurance programs, and information technology implementations; and explains the importance of pharmacy technician education, training, and certification in obtaining innovative positions. *ASHP membership is not required to participate in this program. Go to <http://www.ashpmedia.org/symposia/innovation/overview.html> for more information.

References from ACE-I, ARB continued from page 6.

2. McMurray JJ, Ostergren J, Swedberg K, et al. Effects of candesartan in patients with chronic heart failure and reduced left-ventricular systolic function taking angiotensin-converting-enzyme inhibitors: the CHARM-Added trial. *Lancet* 2003; 362:767-771.
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Continued from Policy, page 5.

prior to becoming a PIC. This will require community pharmacy PICs to have the same level of practice experience as hospital pharmacy PICs.

At the national policy level, on March 28th the American Pharmacists Association (APhA) voted to endorse their leadership to begin coordinating processes that will lead to the development of an accreditation process for all pharmacies in the United States. The APhA is not looking to become an accrediting agency, but rather is concerned that these accreditation standards are being developed outside of the profession. Additionally, the organization voted to endorse making influenza vaccination a condition of employment for health care workers.

The American Society of Health Systems Pharmacists (ASHP) is continuing to fight for reductions in REMS obligations focusing on the new opiate related rules being put forward by FDA. In particular ASHP is continuing to attempt to obtain hospital exemptions for the distribution of medication guides. It is important to note that since medication guides are considered part of a drug product's labeling that is intended for the patient, a failure to dispense a medication guide would constitute misbranding. To date the FDA has not attempted enforcement at the patient by patient level of this regulation.