



LA HEALTH-SYSTEM PHARMACIST

Newsletter of the Louisiana Society of Health-System Pharmacists

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FROM THE DESK OF THE PRESIDENT

I want to thank Dr. Marty Steffenson, our president-elect, for writing the last article for me while I was out on family medical leave. I had visited my terminally ill mother for two and half months overseas. She passed away this summer. Thanks to the understanding of our colleagues, the committees, and board members, I did spend some quality time with her. We have postponed our summer retreat at Alexandria and rescheduled the strategic planning meeting in Baton Rouge for September 22, 2007. I apologize for all the inconveniences this has created for our committee and board members. I also want to give special thanks to Kati, our LSHP coordinator and Helen Calmes who communicated diligently with me during my absence.

Our strategic planning meeting will include collaborative practice, integrating with other professionals and developing future leaders for our profession. In regards to collaborative practice, we will review the final wording and see what kind of opportunities we can engage in. We will also look into what the best practices in the nation are to benefit from other states experiences and success stories. After we aggregate all the information, we will develop our implementation plan. The next two years are very crucial for us to lay the foundation for the practice.

Another area that I think is very important is to market our profession to our peers. We need to gain our administrators' support. For those of us who work in a hospital or clinic setting, we know without the administrators' support, the clinical program will go nowhere. By implementing collaborative practice, we will also help to accomplish JCAHO standards. We all heard that in 2009, warfarin monitoring and DVT prophylaxis will be added to JCAHO standards and CMS core measures. Patients' quality of care and safety are big issues and definitely will not disappear for a long time.

Developing future leaders for our profession is also an important goal that we want to continue to retune and carry on. It has taken many years for our Pharmacy Support Personnel to develop into certified Pharmacy Technicians. It has been a long and winding journey, but we have not yet reached our destination. Some hospitals

have career ladder development for the technicians. However, when they reach the top of the ladder, do they still have room for development? They surely do. They always have a chance to get into pharmacy school and become pharmacists. I have seen a few technicians who have gotten into pharmacy school and become pharmacists. I am proud of them. When I receive a resignation letter or job reassignment letter from a technician, and am told that they had been accepted into a pre-pharmacy or pharmacy program, I am thrilled and happy for them. Who else is more qualified than a master sergeant to get accepted into officer academy.

I am blessed with two excellent student chapters. I must thank Dr. Chris Betz, our immediate past president, who laid the solid foundations for these two chapters. I have been receiving e-mails from them. They both actively participate in our LSHP functions and have made excellent recommendations. Their suggestions will be on our agenda for the board meeting.

A residency for all new pharmacists is also another hot topic on ASHP's agenda. All newly graduated pharmacists must go through a residency program by 2020? We are having a Residency Learning System (RLS) program during our Midyear meeting at Shreveport. I definitely will attend and follow up with it.

I hope to see you all at the Midyear meeting!

Barries Leung, Pharm.D.
President



INSIDE

Mid Year Meeting Information.....	2
Mid Year Meeting Schedule at a glance.....	3
Myelodysplastic Syndromes.....	4-5
Technician's Corner.....	5
Zelnorm Withdrawal from Market.....	6
Controversy:MDRD vs. Cockcroft and Gault.....	7-8

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VACANT

**The LSHP 2007
Midyear Meeting
October 6
Sam's Town
Shreveport, LA
with special activities
October 4 & 5**

To register:

go to the LSHP website at www.lshp.org and click the "Meetings" link to download a brochure, or call the LSHP office at 225-922-4520.

Experience:

the ASHP Residency Learning System, offered on Thursday, October 4. Attendance is limited, so register today! See the brochure for more information!

Soak up:

food & fun at the Welcome Reception and Red River Revel Friday October 5!

Stay:

at Sam's Town Hotel & Casino. Call (877) 429-0711 for reservations. Mention the code *S10 LSP* when you call!

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

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

The 2007 LSHP Midyear Meeting Schedule at a glance

Saturday, October 6, 2007

7:00-8:00 A.M.	Registration/Continental Breakfast
8:00-9:00 A.M.	Gender Differences in Pharmacotherapy Emily Evans, PharmD Contact Hours: 1 OR Vaccine Updates & Recommendations Jessica Staples, PharmD Contact Hours: 1
9:00-10:00 A.M.	Inflammation in Chronic Heart Failure: New Prospects for Therapy? Roy Parish, PharmD, B.C.P.S. Contact Hours: 1 OR Thrombosis Etiology and Treatment in Special Populations: Obesity, Renal Failure and Pregnancy Ernest Lawson, PharmD Contact Hours: 1
10:00-11:00 A.M.	Sedation and Analgesia in the Intensive Care Unit Kelli Sorrells, PharmD Contact Hours: 1 OR Demystifying Medicare Part D: A Guide to Providing Patient Information Spencer Landis, PharmD Contact Hours: 1
11:00 A.M. -1:00 P.M.	Lunch and Exhibits
1:00-3:00 P.M.	Understanding the USP Process and the Recent Changes to USP Chapter <797> Eric Kastango, MBA, RPh, FASHP Contact Hours: 2 OR 1:00-2:00 P.M. Low Health Literacy: Is this a Problem in America and How Does it Affect Patient Care in the Health Care System? LaTonya Menefee, PharmD Contact Hours: 1 AND 2:00-3:00 P.M. Hypercholesterolemia (Dyslipidemia) Christina Victor, PharmD Contact Hours: 1
3:00-4:00 P.M.	Evidence-Based Strategies for Improving Patient Outcomes: Antithrombotic Therapy in the Prevention and Management of Venous Thromboembolism Lynda Thomson, PharmD, CACP Contact Hours: 1 OR Antibiotic Resistance– An Increasing Threat Alexander Bryant, PharmD Contact Hours: 1
4:00-5:00 P.M.	Legal Update: Prescription Monitoring Program Lois Anderson, PharmD, MBA Contact Hours: 1 OR Focus on Newer Antidiabetes Agents and Their Effects on Glycemic Control Carole Pickett, PharmD Contact Hours: 1

Review: Myelodysplastic Syndromes

By Lisa Bertucci, Pharm.D.

The Myelodysplastic Syndromes (MDS) are a group of hematopoietic abnormalities that arise in the bone marrow. MDS often presents as an anemia that is refractory to treatment. However, MDS may affect any or all of the three hematopoietic cell lines, resulting in neutropenia and/or thrombocytopenia as well.

Though MDS often progresses to Acute Myeloid Leukemia (AML), morbidity and mortality are more often due to complications arising from the cytopenias (fatigue, shortness of breath, propensity to bruise easily, bleeding risks, and infections) rather than from the transformation to AML. However, patients who do progress to AML are less responsive to treatment than other individuals presenting with primary AML.

PRESENTATION & DIAGNOSIS

MDS is primarily a disease of the elderly, though it may occur at any age. The cause of these disorders is unknown. However, de novo MDS has been associated with exposure to certain chemicals or viruses; whereas, secondary syndromes often result from previous treatment with alkylating agents or radiation.

Regardless of cause, MDS generally presents with symptoms consistent with their cytopenias. Upon examination of a peripheral blood smear, morphologic changes may be noted in one or all of the cell types. Bone marrow aspiration will often show hypercellularity [increased immature cell (blast) percentages], though a few patients will have hypocellular bone marrow. Cytogenetic studies of the bone marrow are performed to determine the karyotype of the MDS patient.

The World Health Organization (WHO) criteria divide MDS into 8 separate classifications. A full explanation of each type is beyond the scope of this article; however, it is important to note that MDS with 5q abnormality is made a distinct subtype, perhaps due to its relatively good prognosis and specific treatment choice. Also, in the WHO classification system, patients with marrow blasts $\geq 20\%$ are considered to have AML.

PROGNOSIS

The International Prognostic Scoring System (IPSS) was created to score patients based on certain characteristics (percentage blasts, chromosomal abnormalities/karyotype, and number of cytopenias) and to then place them into four risk groups based on that score. Risk groups include low, intermediate-1, intermediate-2, and high risk. Overall median survival based on these categories is reported as follows 5.7 years for low risk, 3.5 for intermediate-1, 1.2 for intermediate-2, and 0.4 for high. Time to progression to AML for 25% of patients was also determined for each risk group: 9.4 years for low risk, 3.3 years for intermediate-1, 1.1 years for intermediate-2, and 0.2 years for high.

Other factors affecting prognosis include age, performance status, and changes in the p53 gene, which tends to carry a worse prognosis.

Determining prognosis is important in order to determine the best course and intensity of treatment.

AVAILABLE TREATMENTS

The main goals of MDS treatment are to control symptoms while improving quality of life and survival and decreasing progression to AML. Specific goals for treatment differ depending on risk score. Low and intermediate-1 risk patients aim for hematological improvement; whereas, patients at intermediate-2 and high risk focus more on preventing disease progression.

Supportive Care

All patients are candidates for supportive care, including clinical monitoring, psychosocial support, and quality of life assessments. For patients with symptomatic anemia, blood transfusions are a mainstay of care. For patients receiving chronic RBC transfusions, iron status must be monitored to prevent overload. Chelation therapy may be warranted with either subcutaneous deferoxamine (Desferal®) or the oral chelator, deferasirox (Exjade®).

Platelet transfusions may be necessary for patients with severe thrombocytopenia or bleeding. Aminocaproic acid may be used for refractory cases.

Patients suffering from neutropenia may benefit from G-CSF or GM-CSF use, though a great response was not seen in MDS patients. Furthermore, patients at significant risk of infection or suspected of having an infection should be treated with appropriate antibiotic therapy.

Treatment of Symptomatic Anemia with EPO

Other causes of anemia, such as active bleeding and nutritional deficiency (iron, vitamin B₁₂, folate), must first be assessed. Also, patients with HLA-DR15 typing should be determined as these patients will benefit from immunosuppressive therapies instead.

Following correction of other possible abnormalities, patients with serum EPO levels ≤ 500 mU/ml may benefit from high doses of EPO therapy (40,000-60,000 units SQ 2-3 times per week). A response should be seen in 6-8 weeks. If no response occurs, some patients may benefit from addition of G-CSF. Generally, lower than standard doses of G-CSF are needed (Average: 1-2 mcg/kg SQ daily or 2-3 times per week).

Hypomethylating Agents

Hypomethylating agents work by demethylation or hypomethylation of DNA in abnormal cells, which allows expression of tumor suppressor genes previously silenced by the methylation. The agents may also have a direct cytotoxic effect on affected cells. These agents are considered low-intensity therapy.

Azacitidine (Vidaza®) is a pyrimidine analogue of cytidine, dosed at 75mg/m² SQ daily for 7 days every 4 weeks for a minimum of four cycles and treatment continuation for as long as effective and tolerated.

Decitabine (Dacogen®) is a second hypomethylating agent given at 15mg/m² IV every 8 hours for 3 days in six week cycles. A minimum of four cycles is suggested and treatment may continue as long as it is tolerated and a response is seen.

Both azacitidine and decitabine showed hematological

response and a prolongation in time of progression to AML. Both improved quality of life and in higher risk patients may have improved survival. Common adverse effects of hypomethylating agents include neutropenia, thrombocytopenia, anemia, and some GI effects. Note that hospitalization is required for treatment with decitabine due to the current regimen being given IV every 8 hours for 3 days.

Immunomodulators

Immunomodulators are thought to be useful in MDS due to their effects on inflammatory cytokine expression, effects on angiogenesis, direct cytotoxic effects, and ability to modulate immune cells. Immunomodulators are also considered low-intensity therapy.

Lenalidomide (Revlimid®) is an analogue of thalidomide that has shown erythropoietic responses, especially in patients with 5q deletion abnormality. In fact, given the availability of lenalidomide treatment, 5q- karyotype has a favorable prognosis. As such, lenalidomide is FDA approved in transfusion-dependent MDS patients with 5q abnormality. Dose-limiting side effects include thrombocytopenia and neutropenia, especially in patients with renal dysfunction. While lenalidomide is not reported to have the same teratogenic side effects as thalidomide, a special distribution program, RevAssist, is in place for users of lenalidomide.

Thalidomide has also been studied in MDS. However, an unfavorable risk/benefit ratio prevents its recommendation for use in MDS. Major side effects included neurotoxicity and fatigue.

Special Cases

Some patients, especially younger patients with HLA-DR15 type and marrow hypoplasia, benefit from the use of immunosuppressive drugs such as anti-thymocyte globulin (ATG) with or without cyclosporine.

High Intensity Therapies

High intensity therapies are usually reserved for high risk patients that can tolerate them based on age and performance status. These treatments include either intensive induction chemotherapy similar to that used for AML or allogeneic hematopoietic stem cell transplants (HSCT) in patients with

suitably matching donors.

Timing of HSCT has been debated. Currently, it is suggested that high risk patients ≤ 60 years old should proceed to transplant at diagnosis of MDS if possible. Low or intermediate -1 risk patients should delay transplantation until their disease progresses.

CONCLUSION

MDS is a complex and varied group of hematopoietic disorders. As such, treatment must be determined by careful consideration of the individual patient. The previous overview does not touch on all treatments available as new treatments continue to be evaluated. One such treatment on the horizon is tipifarnib, a specific farnesyltransferase inhibitor, that is showing promise in the treatment of MDS.

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Technician's Corner

National Pharmacy Technician Day

The 17th Annual National Pharmacy Technician Day is Tuesday, October 23, 2007! This day occurs within National Pharmacy Week; recognize your technicians for the hard work that they do in the pharmacy! ASHP will highlight how technician education leads to safe medication distribution.

The PTCB Exam

The last application window of 2007 has opened. Apply online at www.ptcb.org

Application Window Opens	Application Deadline	Testing Window Opens	Testing Window Ends
Sept. 17	Nov. 2	Nov. 23	Dec. 28

Zelnorm® Withdrawal from US Market

By Ariane Conrad, Pharm.D.

On March 30, 2007, the Food and Drug Administration (FDA) announced that it had requested a voluntary discontinuation of the marketing of Zelnorm® (tegaserod) by its manufacturer, Novartis Pharmaceuticals Corporation. The request was made based on recently discovered information identifying that tegaserod treated patients may be at an increased risk of cardiovascular adverse events when compared to patients that have not been treated with tegaserod. The medication will still be available in the other countries in which it is marketed.

Zelnorm® received FDA approval on July 24, 2002 for the short-term treatment of irritable bowel syndrome (IBS) with constipation as the primary symptom in women. It received approval 2 years later for the treatment of chronic idiopathic constipation in women and men younger than 65 years of age.

The FDA received information from Novartis based on a recent review of 29 studies which involved over 18,000 patients (~11,600 patients received Zelnorm®). The analysis showed a higher risk of angina, myocardial infarction, and strokes associated with the use of Zelnorm® in comparison to the patients receiving placebo. Thirteen Zelnorm® treated patients (0.1%) were diagnosed with cardiovascular ischemic events while only 1 patient (0.01%) was diagnosed with an event from the placebo group. Primarily, these events were seen in patients who had pre-existing cardiovascular disease and/or cardiovascular risk factors. After reviewing the data, the FDA determined that this information proved that the risk of this drug outweighed the benefits.

Novartis has been working with the FDA to possibly allow the use of Zelnorm® in patients with

no other treatment options available on an investigational basis. On July 27, 2007, the FDA announced that it will be permitting the restricted use of Zelnorm® under a treatment investigational new drug (IND) program to treat IBS with constipation and chronic idiopathic constipation in women younger than 55 who meet specific guidelines. These patients must not have had a satisfactory response to other available treatments and/or have shown reasonable improvement of symptoms in the past with Zelnorm®. Patients to be excluded from the program include those with a history of cardiovascular (CV) ischemic disease, current CV ischemic disease or symptoms possibly suggesting CV ischemic disease, and those with uncontrolled depression/anxiety or suicidal ideation. Program materials including information for the physician and the patient will be provided to help ensure that all parties are informed about the potential risks and benefits of Zelnorm®.

Patients who are taking Zelnorm® should be referred to their physician for other treatment options. Inform these patients that Novartis is offering to reimburse patients for their out of pocket costs associated with any unused and unexpired Zelnorm® tablets. Patients should call 1-888-NOW-NOVA (1-888-669-6682) in order to receive the customer product return form. They must return the form and the unused tablets with their prescription receipt by September 30, 2007 to qualify for reimbursement. Patients allowed to participate in the treatment IND program will be provided medication at no cost from Novartis.

References are available upon request.

National Pharmacy Week is October 21-27, 2007!

National Pharmacy Week is approaching! Do you have your activities planned? National Pharmacy Week is a great opportunity to celebrate your profession and promote the safety and well-being of your patients.

LSHP will again offer ribbons advertising Pharmacy Week to all institutions. Visit www.ashp.org for ideas to assist you in planning a successful Pharmacy Week!

Pharmacy Controversy: MDRD versus Cockcroft and Gault in Determining Renal Function: What do you think?

By Treavor Riley, Pharm.D. & Mary Gauthier-Lewis, Pharm.D.
ULM College of Pharmacy

The glomerular filtration rate (GFR) is traditionally considered the best overall index of renal function in healthy and diseased individuals. GFR, however, is difficult to measure in clinical practice. Because of this, strides have been taken to estimate GFR from serum creatinine. Despite more recent studies relating serum creatinine to GFR, no equation has been more widely used to predict creatinine clearance than that proposed by Cockcroft and Gault. Currently, this formula is used to detect the onset of renal insufficiency, to adjust the dose of renally excreted drugs, and to evaluate the effectiveness of therapy for progressive renal disease.

Unfortunately, the Cockcroft and Gault formula has its flaws. Studies have shown that serum creatinine concentration is affected by more than just creatinine filtration. Older age and female sex are both independent predictors of lower GFR. One expects an elderly individual or a female to have less muscle mass than a younger individual or a male respectively. The Cockcroft and Gault formula takes these variables into account. It does not, however, account for urine urea nitrogen excretion or protein intake, both being independent predictors of lower GFR. It also fails to account for ethnicity. Black ethnicity is an independent

predictor of a higher GFR. With all of these variables unaccounted for, should another method be sought after for estimation of GFR?

The Modification of Diet and Renal Disease (MDRD) Study was conducted to establish a formula that would not only be a better estimation of GFR, but to also be used as the standard for detection and diagnosis of renal insufficiency and adjustment of renally excreted drugs. In one study conducted by Levey et al. for the MDRD study group, seven different derived equations were used and evaluated to see which would yield a significantly closer estimation to GFR (Table 1). Of these seven equations, the most precise was the multiple regression model that included urine biochemistry variables (equation 6). The model derived from only demographic and serum biochemistry values was only slightly less precise (equation 7). The two equations were significantly more accurate at estimating GFR than all others involved in the study, including the Cockcroft and Gault formula. Equation 7, however, does not require urine collection, making it a more practical choice with near equal accuracy. For this reason, it is the MDRD's equation for estimation of GFR.

Table 1. Comparison of Equations to Predict (ml/min/1.73 m²) from Serum Creatinine Concentration

Equation 1: Serum Creatinine	$GFR = 0.69 \times [100/Scr]$
Equation 2: Cockcroft-Gault Formula	$GFR = 0.84 \times [(170 - \text{age}) \times BW] / (72 \times Scr)$
Equation 3: Creatinine Clearance	$GFR = 0.81 \times C_{cr}$
Equation 4: Average of C _{cr} and C _{urea}	$GFR = 1.11 \times [(C_{cr} + C_{urea}) / 2]$
Equation 5: C _{cr} , C _{urea} , demographics	$GFR = 1.04 \times [C_{cr}]^{0.751} \times [C_{urea}]^{0.226} \times [1.109 \text{ if patient is black}]$
Equation 6: Demographic, serum, and urine variables	$GFR = 198 \times [S_{cr}]^{-0.858} \times [Age]^{-0.167} \times [0.822 \text{ if patient is female}] \times [1.178 \text{ if patient is black}] \times [BUN]^{-0.293} \times [UUN]^{0.249}$
Equation 7: Demographic, and serum variables only	$GFR = 170 \times [S_{cr}]^{-0.999} \times [Age]^{-0.176} \times [0.762 \text{ if patient is female}] \times [1.180 \text{ if patient is black}] \times [BUN]^{-0.170} \times [Alb]^{0.318}$

Alb= serum albumin concentration (g/dL), C_{cr}= creatinine clearance (ml/min/1.73 m²),

C_{urea}= urea clearance (ml/min/1.73 m²), Scr= serum creatinine concentration (mg/dL),

BUN = blood urea nitrogen concentration (mg/dL), UUN= urine urea nitrogen concentration (gm/dL)

Table Adapted from Levey et al.

The National Kidney Foundation (NKF) and the National Kidney Disease Education Program (NKDEP) have implemented a new serum creatinine assay standardization set to take effect in 2008. The purpose of this standardization is to more accurately measure serum creatinine and ultimately yield better measurements for estimations of GFR. The NKF currently recommends adoption of the new MDRD equation to estimate GFR in patients with chronic kidney disease.

They also require that the estimation be included in routine chemistry and lab reports. Because the new assay standardization will yield different results than those previously evaluated by drug companies, new ranges for dosage adjustments must be evaluated to better treat the patient.

Continued from Pharmacy Controversy, Page 7

With the new serum creatinine assay becoming standard in 2008 and the MDRD equation yielding a closer estimation to GFR than previously seen, more accurate diagnoses and therapeutic adjustments will be made.

Should the MDRD equation replace Cockcroft-Gault?

What is your opinion?

Please send your thoughts and comments to djamer@xula.edu or LSHP 8550 United Plaza Blvd, Suite 1001 Baton Rouge, LA 70809.

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In Memoriam:

LSHP wishes to remember Carla Marie Luke, a past member, and a clinical pharmacist at the Veterans Administration Hospital of New Orleans. Dr. Luke passed away August 29, 2007 at the age of 53. Dr. Luke was formerly a professor at Xavier University and a clinical education consultant for Pharmacia and later Pfizer. She is survived by her parents, and her twin sister, Dr. Carlen McLin, an associate professor of Public Health at Dillard University who has participated in several LSHP meetings. A Mass of Christian Burial was celebrated September 8.