New and Emerging Strategies for the Treatment of Chronic Heart Failure: A Clinical Case Studies Workshop

Presented as a Midday Symposium and Live Webinar at the 51st ASHP Midyear Clinical Meeting and Exhibition

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www.ashpadvantage.com/go/chf

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Agenda

11:30 a.m. – 11:50 a.m.
Welcome and Introductions – Setting the Stage

11:50 a.m. – 12:50 p.m.
Clinical Cases Workshop including Questions and Answers

12:50 p.m. – 1:00 p.m.
Wrap Up

Faculty

Robert J. DiDomenico, Pharm.D., BCPS-AQ Cardiology, FCCP, Activity Chair
Clinical Professor
College of Pharmacy
University of Illinois at Chicago
Cardiovascular Clinical Pharmacist
University of Illinois Hospital
Chicago, Illinois

Jo E. Rodgers, Pharm.D., BCPS-AQ Cardiology, FCCP, FHFSA
Clinical Associate Professor
University of North Carolina Eshelman School of Pharmacy
Chapel Hill, North Carolina
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About the Series

Heart failure is a complex clinical syndrome. This series of educational activities on chronic heart failure begins by reviewing basic concepts, pharmacologic strategies, and new and emerging therapies. (Part 1 of the series now available on-demand at www.ashpadvantage.com/go/chf). The series continues with this clinical workshop that will use patient case scenarios to illustrate how complications, dosing, patient parameters, and other factors affect therapy in heart failure.

Activity Overview

In this symposium and simultaneous live webinar, faculty will conduct a clinical workshop using patient scenarios to illustrate how complications, dosing, patient parameters, and other factors affect therapy in heart failure. The cases will follow patients from the beginning of the disease and beyond, when complications arise and more than one approach to therapy might be considered. Participants will be given the opportunity to test their knowledge in the management of heart failure throughout the highly interactive program. The symposium and webinar will include a pretest and posttest to assess participants’ baseline knowledge. Participation in the first activity of the series is strongly encouraged as preparation for the clinical workshop where participants will expand and enhance the skills and knowledge needed in real-world clinical scenarios.

Learning Objectives

At the conclusion of this application-based educational activity, participants should be able to

- Review the key assessments of a patient’s disease status to determine appropriate drug selection, dosage, and monitoring.
- Outline the role of the new medications in managing chronic heart failure.
- Using patient scenarios, apply the pharmacist’s role in the management of chronic heart failure.
- Recommend appropriate management of chronic heart failure based on updated guidelines.
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Continuing Education Accreditation

The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

This activity provides 1.5 hours (0.15 CEUs – no partial credit) of continuing pharmacy education credit.

Live Activity ACPE #: 0204-0000-16-467-L01-P
On-Demand Activity ACPE #: 0204-0000-16-467-H01-P

Complete instructions for processing continuing education credit online are listed on the last page.

Webinar Information

Visit www.ashpadvantage.com/go/chf to find:

• Webinar registration link
• Group viewing information and technical requirements

GET THE MOST FROM THIS 2-PART SERIES

• Part 1 – Overview Activity – Contemporary Approaches to the Management of Chronic Heart Failure: An Overview – Available now on-demand (1.0 hour CPE)

• Part 2 – Case Clinical Workshop - Based on today’s live symposium – Coming in March 2017 (1.5 hours CPE)

Please note that individuals who claim CPE credit for the live symposium or webinar are ineligible to claim credit for the web-based activity.

For more information, visit http://www.ashpadvantage.com/go/chf
New and Emerging Strategies for the Treatment of Chronic Heart Failure:
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Faculty

Robert J. DiDomenico, Pharm.D., BCPS-AQ Cardiology, FCCP
Clinical Professor
College of Pharmacy
University of Illinois at Chicago
Cardiovascular Clinical Pharmacist
University of Illinois Hospital
Chicago, Illinois

Robert J. DiDomenico, Pharm.D., FCCP, is Clinical Professor in the Department of Pharmacy Practice, and Faculty of the Center for Pharmacoepidemiology and Pharmacoeconomic Research at the University of Illinois at Chicago (UIC). He is also Cardiovascular Clinical Pharmacist at the University of Illinois Hospital & Health Sciences System with a practice site in inpatient cardiology. Dr. DiDomenico serves as Residency Program Director for the UIC PGY2 Cardiology Pharmacy residency. Since 2008, he has chaired the Educational Policy Committee at the UIC College of Pharmacy.

Dr. DiDomenico received his Pharm.D. and completed three years of post-doctoral training (Pharmacy Practice Residency, Cardiovascular Pharmacotherapy Fellowship) at UIC.

Dr. DiDomenico has authored more than 80 peer-reviewed articles, book chapters, and abstracts on topics related to cardiovascular pharmacotherapy and has gained national recognition as a key opinion leader in the areas of heart failure, anticoagulation, and coronary artery disease. He is also an active member of several organizations including the American College of Clinical Pharmacy, American College of Cardiology, and the Heart Failure Society of America.
Jo E. Rodgers, Pharm.D., BCPS-AQ Cardiology, FCCP, FHSA
Clinical Associate Professor
University of North Carolina Eshelman School of Pharmacy
Chapel Hill, North Carolina

Jo Ellen Rodgers, Pharm.D., BCPS-AQ Cardiology, FCCP, FHSA, is Clinical Associate Professor at the University of North Carolina (UNC) Eshelman School of Pharmacy. She is also Associate Director of clinical fellowship programs in the Division of Pharmacotherapy and Experimental Therapeutics.

Dr. Rodgers obtained her Bachelor of Science degree in pharmacy and her Doctor of Pharmacy degree at the University of North Carolina at Chapel Hill. She completed a pharmacy practice and critical care specialty residency at the Medical College of Virginia, followed by a fellowship in cardiovascular pharmacotherapy at UNC.

Dr. Rodgers maintains an active clinical practice with the UNC Cardiomyopathy and Cardiac Transplant Service at UNC Hospitals. Her primary research interest is in the care of heart failure patients.

Dr. Rodgers has served on the American College of Clinical Pharmacy (ACCP) Board of Regents. She is a fellow of the ACCP and the Heart Failure Society of American (HFSA) and has been recognized as a Distinguished Practitioner and Fellow of the National Academies of Practice. Dr. Rodgers currently serves on the Guideline Committee of the HFSA and as incoming Chair of the Board of Pharmacy Specialties Pharmacotherapy Specialty Council.
A Clinical Case Studies Workshop

Robert J. DiDomenico, Pharm.D., BCPS-AQ Cardiology, FCCP
Clinical Professor, University of Illinois at Chicago College of Pharmacy
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Learning Objectives

• Review the key assessments of a patient’s disease status to determine appropriate drug selection, dosage, and monitoring.
• Outline the role of the new medications in managing chronic heart failure (CHF).
• Using patient scenarios, apply the pharmacist’s role in the management of chronic heart failure.
• Recommend appropriate management of chronic heart failure based on updated guidelines.
Heart Failure Pathophysiology & Treatment Options

- Pathophysiology
  - Neurohormonal activation
    - Renin-angiotensin-aldosterone system (RAAS)
    - Sympathetic nervous system
    - Vasopressin
  - Hemodynamic adaptations
    - Increased preload
    - Increased afterload
    - Decreased contractility
      - Heart failure with reduced ejection fraction (HFrEF)

- Guideline-Directed Medical Therapy (GDMT)
  - Anti-RAAS agents
    - Angiotensin converting enzyme inhibitors (ACEI)
    - Angiotensin receptor blockers (ARB)
    - Aldosterone receptor antagonists (ARA)
  - Angiotensin receptor neprilysin inhibitor (ARNI)
    - Sacubitril/valsartan
  - Beta-blockers
  - Nitrates/hydralazine
  - Diuretics
  - Digoxin

Evidence-based Assessments to Guide Use of Heart Failure Medications

- Left ventricular ejection fraction (LVEF)
- Signs & symptoms during each encounter
  - Determine functional class!
- Vital signs during each encounter
- Renal function, electrolytes
- Adherence & related barriers
  - Medications, diet
  - Social support, insurance/affordability, poor cognition

Stages of Heart Failure & Functional Classification

- Heart Failure (HF) Stages
  - Stage A
    - At risk for HF, no structural disease or symptoms
  - Stage B
    - Structural heart disease, no signs or symptoms of HF
  - Stage C
    - Structural heart disease with prior/current symptoms of HF
  - Stage D
    - Refractory HF requiring specialized interventions

- New York Heart Association (NYHA) Functional Classification
  - Class I
    - Asymptomatic with normal activity
  - Class II
    - Comfortable at rest, symptoms with normal activity
  - Class III
    - Comfortable at rest, symptoms with less than normal activity
  - Class IV
    - Symptoms at rest

Specific Activity Scale Functional Class

Can you do any of these without stopping?
- Carry anything up 8 steps
- Sexual intercourse
- Gardening
- Roller skate/dance
- Walk 4 miles/hour

Yes No

Goldman LE. Circulation. 1981; 64:1227-34.

Evidence-based Heart Failure Medications: Place in Therapy

Asymptomatic (Stage B, Class I)
- ACE inhibitor
- ARB
- Sacubitril/valsartan
- Beta-blocker

Symptomatic (Stage C, Class II-IV)
- African American, Class III/IV – Add ISDN/Hydralazine
- Class II-IV – Replace ACE/ARB with Sacubitril/valsartan – Add ARA
- Diuretics
- Ivabradine
- Digoxin

ISDN=isosorbide dinitrate


Recommendation Class and Evidence Level

<table>
<thead>
<tr>
<th>Class (Strength) of Recommendation (COR)</th>
<th>Level (Quality) of Evidence (LOE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I (Strong): BENEFIT &gt;&gt; RISK</td>
<td>Level A (High quality evidence from more than 1 RCT)</td>
</tr>
<tr>
<td>Class IIa (Moderate): BENEFIT &gt;&gt; RISK</td>
<td>Level B-R (RANDOMIZED) (Moderate quality evidence from 1 or more RCT)</td>
</tr>
<tr>
<td>Class IIb (Weak): BENEFIT &gt; RISK</td>
<td>Level B-NR (NONRANDOMIZED) (Moderate quality evidence from 1 or more NRCT)</td>
</tr>
<tr>
<td>Class III: No Benefit (Moderate): BENEFIT = RISK</td>
<td>Level C-LD (LIMITED DATA) (Randomized or nonrandomized observational or registry studies with limitations)</td>
</tr>
<tr>
<td>Class IV: Harm (Strong): RISK &gt; BENEFIT</td>
<td>Level C-EO (EXPERT OPINION) (Consensus of expert opinion based on clinical experience)</td>
</tr>
</tbody>
</table>

RCT=randomized controlled trial, NRCT=nonrandomized controlled trial


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Sacubitril/Valsartan

What Do We Know & What Questions Remain Unanswered?

PARADIGM-HF Clinical Outcomes

PARADIGM-HF: Who Was Studied?

- Adults with left ventricular ejection fraction ≤35-40%
- NYHA class II-IV symptoms
- BNP ≥150 pg/mL or NT-proBNP ≥600 pg/mL or HF hospitalization in last 12 months
- ACEI or ARB x 4 weeks
- Estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73m²

Single-blind enalapril 10 mg BID x 2 weeks
Enalapril washout x 1 day

Single-blind sacubitril/valsartan 100–200 mg BID x 4 – 6 weeks

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Post-Marketing Selection of Sacubitril/Valsartan Patients

- FDA-approved indication
  - “…indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction.”
  - “…usually administered in conjunction with other heart failure therapies, in place of an ACEI or other ARB”

- FDA label - not PARADIGM-HF vs. PARADIGM-HF criteria
  - Significantly sicker population
  - FDA indication + eGFR <30 (n=19)

- HF readmission 4-fold higher


Sacubitril/Valsartan Doses for HFrEF

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Initial Dose (Maximum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most patients</td>
<td>49/51 mg BID 97/103 mg BID</td>
</tr>
<tr>
<td>Special populations</td>
<td>24/26 mg BID 97/103 mg BID</td>
</tr>
<tr>
<td>• Not on ACEI or ARB</td>
<td></td>
</tr>
<tr>
<td>• On low doses of ACEI or ARB</td>
<td></td>
</tr>
<tr>
<td>• eGFR &lt;30 mL/min/1.73 m²</td>
<td></td>
</tr>
<tr>
<td>• Moderate hepatic impairment</td>
<td></td>
</tr>
</tbody>
</table>

- Do NOT administer within 36 hours of ACEI administration
- Double dose every 2 – 4 weeks, as tolerated, to target dose

Entresto (sacubitril/valsartan) prescribing information. Novartis Pharmaceuticals Corp. 2015 Aug.

PARADIGM-HF
Who Was & Was Not Studied?

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Sacubitril/Valsartan (n=4187)</th>
<th>Enalapril (n=4212)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female gender (%)*</td>
<td>21.0</td>
<td>22.6</td>
</tr>
<tr>
<td>Race (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>66.0</td>
<td>66.0</td>
</tr>
<tr>
<td>Black*</td>
<td>5.1</td>
<td>5.1</td>
</tr>
<tr>
<td>Asian</td>
<td>18.1</td>
<td>17.8</td>
</tr>
<tr>
<td>Other</td>
<td>10.8</td>
<td>11.1</td>
</tr>
<tr>
<td>Region (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>North America</td>
<td>7.4</td>
<td>6.9</td>
</tr>
<tr>
<td>Latin America</td>
<td>17.0</td>
<td>17.1</td>
</tr>
<tr>
<td>Western Europe</td>
<td>24.5</td>
<td>24.3</td>
</tr>
<tr>
<td>Central Europe</td>
<td>33.3</td>
<td>34.0</td>
</tr>
<tr>
<td>Asia-Pacific</td>
<td>17.8</td>
<td>17.6</td>
</tr>
</tbody>
</table>

*Women & African Americans have higher prevalence of ACEI-induced angioedema

Sacubitril/Valsartan: Guideline Recommendations

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>ACC/AHA/HFSA Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>ACE: A</td>
<td>The clinical strategy of inhibition of the RAAS with ACEIs or ARBs or ARNI in conjunction with evidence-based beta-blockers (BB) and ARAs in selected patients is recommended for patients with chronic HFrEF to reduce morbidity and mortality.</td>
</tr>
<tr>
<td>III-Harm</td>
<td>B-R</td>
<td>ARNI should not be administered concomitantly with ACEIs or within 36 hours of the last dose of an ACEI.</td>
</tr>
<tr>
<td>III-Harm</td>
<td>C-E0</td>
<td>ARNI should not be administered to patients with a history of angioedema.</td>
</tr>
<tr>
<td>I</td>
<td>B</td>
<td>Sacubitril/valsartan is recommended as a replacement for an ACEI to further reduce the risk of HF hospitalization and death in ambulatory patients with HFrEF who remain symptomatic despite optimal treatment with ACEI, BB, and ARA.</td>
</tr>
</tbody>
</table>


Cost-Effectiveness of Sacubitril/Valsartan

- **Dementia Risk?**
  - Neprilysin degrades amyloid-β (Aβ) peptide in the brain
  - Neprilysin inhibition may increase Aβ & plaque-like deposits in the brain
  - Neprilysin inhibition may result in dementia or cognitive impairment

- **Cerebral Safety?**
  - 43 healthy subjects treated with sacubitril/valsartan x 14 days
  - No change in aggregable Aβ isoforms vs. placebo
  - 42% increase in soluble Aβ vs. placebo

Sacubitril/Valsartan & Dementia?


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Sacubitril/Valsartan Summary

• More effecting than ACEI in reducing cardiovascular events in patients with HFrEF
  – May change the standard of care
• Questions remain
  – Safety in ACEI/ARB naïve patients
  – Safety & efficacy in unstudied/understudied/sicker populations included in the FDA-approved indication
  – Cost-effectiveness
  – Dementia risk?

New and Emerging Strategies for the Treatment of Chronic Heart Failure

Ivabradine
What Do We Know & What Questions Remain Unanswered?

Ivabradine in HFrEF: SHIFT Trial Outcomes
SHIFT: Who Was Studied?

Primary endpoint: CV death or hospitalization for worsening HF

Ivabradine 5 mg BID*  Placebo

*Titrated at 2 weeks based upon HR and tolerability, target HR 50-60 bpm

Median follow-up duration: 22.9 months

SHIFT: Impact on Heart Rate

At study end, HR difference 8.1 bpm (95% CI 7.5-8.7).

Placebo         Ivabradine

64               67

Mean dose at 1 year: 6.5 mg twice daily
Patients on ivabradine 7.5 mg bid: 70%

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SHIFT: Who Was & Was Not Studied?

<table>
<thead>
<tr>
<th></th>
<th>Ivabradine (n=3,241)</th>
<th>Placebo (n=3,264)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean yr, SD)</td>
<td>61 (11)</td>
<td>60 (12)</td>
</tr>
<tr>
<td>Male (%)</td>
<td>76</td>
<td>77</td>
</tr>
<tr>
<td>NYHA II/III (%)</td>
<td>49/50</td>
<td>49/50</td>
</tr>
<tr>
<td>LVEF (mean %, SD)</td>
<td>29 (5)</td>
<td>29 (5)</td>
</tr>
<tr>
<td>Ischemic etiology</td>
<td>68%</td>
<td>67%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>67%</td>
<td>66%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>30%</td>
<td>31%</td>
</tr>
<tr>
<td>History of atrial fibrillation/flutter</td>
<td>8%</td>
<td>8%</td>
</tr>
<tr>
<td>eGFR (mean mL/min/1.73 m², SD)</td>
<td>75 (23)</td>
<td>75 (23)</td>
</tr>
</tbody>
</table>


SHIFT: Comparison to Other Trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>LVEF (%)</th>
<th>NYHA class (%)</th>
<th>SBP (mmHg)</th>
<th>HR (bpm)</th>
<th>ACEI/ARB (%)</th>
<th>Beta-blocker (%)</th>
<th>ARA (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMPHASIS</td>
<td>26</td>
<td>100 II</td>
<td>124</td>
<td>72</td>
<td>93</td>
<td>86</td>
<td>NA</td>
</tr>
<tr>
<td>A-HeFT</td>
<td>24</td>
<td>95% III</td>
<td>126</td>
<td>N/A</td>
<td>87</td>
<td>74</td>
<td>38</td>
</tr>
<tr>
<td>SHIFT</td>
<td>29</td>
<td>49% II, 50% III</td>
<td>121</td>
<td>79</td>
<td>91</td>
<td>89</td>
<td>60</td>
</tr>
<tr>
<td>PARADIGM</td>
<td>&lt;35 [88]</td>
<td>70% II, 24% III</td>
<td>121</td>
<td>72</td>
<td>100</td>
<td>93</td>
<td>56</td>
</tr>
</tbody>
</table>

SBP=systolic blood pressure


SHIFT: Optimization of Beta-blocker

![Graph showing optimization of beta-blocker](image)

SHIFT: Selected Adverse Events

<table>
<thead>
<tr>
<th>Event</th>
<th>Ivabradine n=3232, n (%)</th>
<th>Placebo n=3260, n (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All serious adverse events</td>
<td>1450 (45%)</td>
<td>1553 (48%)</td>
<td>0.025</td>
</tr>
<tr>
<td>All adverse events (AE)</td>
<td>2439 (75%)</td>
<td>2423 (74%)</td>
<td>0.303</td>
</tr>
<tr>
<td>Heart failure</td>
<td>804 (25%)</td>
<td>937 (29%)</td>
<td>0.0005</td>
</tr>
<tr>
<td>Symptomatic bradycardia</td>
<td>150 (5%)</td>
<td>32 (1%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Asymptomatic bradycardia</td>
<td>184 (6%)</td>
<td>48 (1%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>306 (9%)</td>
<td>251 (8%)</td>
<td>0.012</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>130 (4%)</td>
<td>178 (5%)</td>
<td>0.007</td>
</tr>
<tr>
<td>Blurred vision</td>
<td>17 (1%)</td>
<td>7 (&lt;1%)</td>
<td>0.042</td>
</tr>
<tr>
<td>Phosphenes</td>
<td>89 (3%)</td>
<td>17 (1%)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

**AE leading to drug withdrawal:**
- Symptomatic bradycardia 20 (1%) vs. 5 (<1%), p=0.002
- Asymptomatic bradycardia 28 (1%) vs. 5 (<1%), p=0.0001


Ivabradine Cost-effectiveness in U.S.

<table>
<thead>
<tr>
<th>Commercial Population</th>
<th>Ivabradine</th>
<th>Background Therapy</th>
<th>Incremental</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalization costs</td>
<td>$337,268</td>
<td>$375,634</td>
<td>-$38,366</td>
</tr>
<tr>
<td>AE costs</td>
<td>$5294</td>
<td>$2722</td>
<td>$2571</td>
</tr>
<tr>
<td>Drug costs</td>
<td>$27,201</td>
<td>NA</td>
<td>$27,201</td>
</tr>
<tr>
<td>Total costs</td>
<td>$369,762</td>
<td>$378,356</td>
<td>-$8594</td>
</tr>
</tbody>
</table>

- Cost savings of $8594 versus the cost of background therapy alone over a 10-year time horizon, primarily because of reduced hospitalization
- Incremental benefit of 0.24 quality-adjusted life-years (QALYs) over a 10-year time horizon


Ivabradine: Guideline Recommendations

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIa</td>
<td>B-R</td>
<td>Ivabradine can be beneficial to reduce HF hospitalization for patients with symptomatic NYHA class II-III stable chronic HFrEF (LVEF ≤35%) who are receiving GDMT, including a BB at maximum tolerated dose, and who are in sinus rhythm with a HR &gt;70 bpm at rest.</td>
</tr>
</tbody>
</table>

Ivabradine Summary

- Reduces HF and all-cause hospitalization
  - Patients receiving GDMT, including a BB at maximum tolerated dose
  - Patients who are in sinus rhythm with a HR >70 bpm at rest
- Questions remain
  - Mortality benefit if HR >75 bpm
  - Benefit over other advanced HF therapies, specifically digoxin
  - Risk of atrial fibrillation
  - Risk of phosphenes

Guideline Recommendations

<table>
<thead>
<tr>
<th>Sacubitril/valsartan:</th>
<th>LOE</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>COR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>A</td>
<td>ACEI: A, ARB: A ARNI: B-R The clinical strategy of inhibition of the RAAS with ACEIs or ARBs or ARNI in conjunction with evidence-based BBs and ARAs in selected patients is recommended for patients with chronic HFrEF to reduce morbidity and mortality.</td>
</tr>
<tr>
<td>III: Harm</td>
<td>B-R</td>
<td>ARNI should not be administered concomitantly with ACEIs or within 36 hours of the last dose of an ACEI.</td>
</tr>
<tr>
<td>III: Harm</td>
<td>C-EO</td>
<td>ARNI should not be administered to patients with a history of angioedema.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ivabradine:</th>
<th>LOE</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>COR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IIa</td>
<td>B-R</td>
<td>Ivabradine can be beneficial to reduce HF hospitalization for patients with symptomatic (NYHA class II-III) stable chronic HFrEF (LVEF ≤35%) who are receiving GDMT, including a BB at maximum tolerated dose, and who are in sinus rhythm with a HR &gt;70 bpm at rest.</td>
</tr>
</tbody>
</table>

Key Takeaways

- Selection of appropriate guideline-directed medical therapy is dictated by appropriate patient assessment
  - NYHA classification less reliable than other methods
- Sacubitril/valsartan reduces mortality and hospitalization in HFrEF but questions remain
  - Use in poorly studied subgroups
  - Cost-effectiveness
- Ivabradine reduces HF and all-cause hospitalization in HFrEF but questions remain
  - Impact on mortality if HR >75 bpm, benefit over digoxin
  - Cost-effectiveness

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Case 1: JA

- 63 year-old African American female presents for outpatient follow up.
- She was diagnosed with HFrEF during hospitalization for acute heart failure 2 months ago.
- Since that time, her symptoms are stable but still present. She states she is able to ascend/descend a flight of stairs without symptoms but becomes symptomatic when carrying her 20 lb granddaughter to her 2nd floor bedroom. She was able to do so prior to her diagnosis.

Case 1: JA

- PMH
  - HFrEF
  - Hypertension
  - Diabetes
  - Dyslipidemia
  - Chronic kidney disease
- Medications
  - Lisinopril 20 mg daily
  - Carvedilol 12.5 mg BID
  - Bumetanide 1 mg BID
  - Atorvastatin 80 mg daily
  - Insulin glargine 20 units/day
- Vital signs
  - BP 116/78 mmHg
  - HR 54 bpm
- Echocardiogram
  - LVEF 25% (2 months ago)
- Labs
  - Sodium 134 mEq/L
  - Potassium 4.3 mEq/L
  - Creatinine 2.3 mg/dL
  - eGFR ~25 mL/min/1.73m²
- Insurance: PPO
Case Discussion: JA

- What functional class is this patient?
- Is this patient on optimal guideline-directed medical therapy?
  - What, if any, changes would you recommend?
- Is this patient a candidate for sacubitril/valsartan?
  - What, if any, concerns would you have about initiating sacubitril/valsartan?
- If sacubitril/valsartan were started, what is your plan for initiation, titration, and monitoring?

What functional class is JA?

A. Class I  
B. Class II  
C. Class III  
D. Class IV

Specific Activity Scale Functional Class

Can you do any of these without stopping?
- Carry anything up 8 steps
- Sexual intercourse
- Gardening
- Roller skate/dance
- Walk 4 miles/hour

Can you do any of these without stopping?
- Carry 24 lbs up 8 steps
- Carry objects ≥ 80 lbs
- Shovel snow
- Recreational activities/sports
- Jog/walk 5 miles/hour

Can you do any of these without stopping?
- Shower
- Strip/make bed
- Mop floors
- Hang washed clothes
- Clean windows
- Walk 2.5 miles/hour
- Bowl
- Play golf (walking)
- Push power lawn mower

Can you dress yourself without stopping?


See enlargement, p. 32
What, if any, changes would you make to JA’s guideline-directed medical therapy?

A. Add eplerenone
B. Add isosorbide dinitrate/hydralazine
C. Increase carvedilol dose
D. No changes are necessary

What, if any, changes would you make to JA’s guideline-directed medical therapy?

• Add eplerenone
  – Contraindicated with creatinine clearance <30 mL/min
• Add isosorbide dinitrate/hydralazine
  – Reasonable (African American), but class II symptoms
• Increase carvedilol dose
  – May not be feasible with heart rate of 54 bpm
• Other considerations?

Which of the following criteria does JA meet for use of sacubitril/valsartan?

A. FDA labeling
B. PARADIGM-HF inclusion/exclusion
C. Both FDA labeling & PARADIGM-HF criteria
D. Neither FDA labeling nor PARADIGM-HF criteria
FDA Label vs. PARADIGM-HF Criteria?

- PARADIGM-HF
  - Adults with LVEF ≤35-40%
  - NYHA class II-IV symptoms
  - BNP ≥150 pg/mL or NT-proBNP ≥600 pg/mL or HF hospitalization in last 12 months
  - ACEI or ARB x 4 weeks
  - Estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73m²

- FDA Label
  - “…indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction.”
  - “…usually administered in conjunction with other heart failure therapies, in place of an ACEI or other ARB”


Would you switch JA’s lisinopril to sacubitril/valsartan?

A. Yes
B. No
C. Maybe

Would you switch JA’s lisinopril to sacubitril/valsartan?

- Why?
  - HFrEF
  - Class II symptoms on GDMT
  - Recent hospitalization
  - Tolerated lisinopril x 4 weeks
  - Cost-effective

- Why not?
  - eGFR <30 mL/min/1.73m²
  - African American & concerns for angioedema?
  - Cost/cost-effectiveness
If JA was switched to sacubitril/valsartan, how would you do so?

A. Start sacubitril/valsartan 24/26 mg BID, stop lisinopril 36 hours later
B. Stop lisinopril, start sacubitril/valsartan 24/26 mg BID later that evening
C. Stop lisinopril, start sacubitril/valsartan 49/51 mg BID after 2 week washout period
D. Stop lisinopril, start sacubitril/valsartan 24/26 mg BID 36 – 48 hours later

Sacubitril/Valsartan Doses for HFrEF

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Initial Dose</th>
<th>Target Dose (Maximum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most patients</td>
<td>49/51 mg BID</td>
<td>97/103 mg BID</td>
</tr>
<tr>
<td>Special populations</td>
<td>24/26 mg BID</td>
<td>97/103 mg BID</td>
</tr>
<tr>
<td>• Not on ACEI or ARB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Fin dose doses of ACEI or ARB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• eGFR &lt;30 ml/min/1.73 m²</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Moderate hepatic impairment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Do NOT administer within 36 hours of ACEI administration
- Double dose every 2 – 4 weeks, as tolerated, to target dose

Case 2: RS

- 65 year-old Caucasian male is referred from the local community hospital for advanced therapy work-up.
- He was diagnosed with HFrEF 2 years ago, had two HF hospitalizations within the past 6 months.
- Since his diagnosis, RS has experienced a progressive decline in his functional status. He previously walked his dog approximately 1 mile daily, he now experiences DOE and fatigue when retrieving his mail and grocery shopping. He has no SOB at rest. He does admit to reduced mood given ADL limitations.

DOE=dyspnea on exertion, SOB=shortness of breath, ADL=activities of daily living
Case 2: RS

- PMH
  - HFxEF
  - IDCM, ICD in 2015
  - Chronic obstructive pulmonary disease (COPD)
  - Smoking
- Medications
  - Furosemide 40 mg BID
  - Enalapril 2.5 mg BID
  - Metoprolol XL 50 mg daily
  - Fluticasone/salmeterol 500 mcg/50 mcg BID
  - Tiotropium 18 mcg daily
  - Varenicline 1 mg BID
- Vital signs
  - BP 92/58 mmHg
  - HR 95 bpm
- Echocardiogram
  - LVEF 20-25% (8/16)
  - LVEF 30-35% (7/14)
- Labs
  - Sodium 127 mEq/L
  - Potassium 4.7 mEq/L
  - Creatinine 1.7 mg/dL
  - eGFR ~60 mL/min/1.73m²
- Insurance: Medicare Adv

IDCM=idiopathic dilated cardiomyopathy, ICD=implantable cardioverter defibrillator

Case Discussion: RS

- What functional class is this patient?
- Is this patient on optimal guideline-directed medical therapy?
  - What, if any, changes would you recommend?
- Is this patient a candidate for ivabradine? Why or why not?
  - What, if any, concerns would you have about initiating ivabradine?
- If ivabradine was started, what is your plan for initiation, titration, monitoring, and counseling?

What functional class is RS?

A. Class I
B. Class II
C. Class III
D. Class IV
Specific Activity Scale Functional Class

Can you do any of these without stopping?
- Carry anything up 8 steps
- Sexual intercourse
- Gardening
- Roller skate/dance
- Walk 4 miles/hour
- Sexual intercourse
- Gardening
- Roller skate/dance
- Walk 4 miles/hour

Can you do any of these without stopping?
- Carry 24 lbs up 8 steps
- Carry objects ≥ 80 lbs
- Shovel snow
- Recreational activities/sports
- Jog/walk 5 miles/hour

Class III
Class II
Class I
Class IV


See enlargement, p. 32

What, if any, changes would you make to RS’s GDMT?

A. Switch enalapril to sacubitril/valsartan
B. Increase enalapril dose
C. Increase metoprolol dose
D. Add spironolactone

What, if any, changes would you make to RS’s GDMT?

- Switch enalapril to sacubitril/valsartan
  - Limited by low blood pressure
- Increase enalapril dose
  - Limited by low blood pressure, after ARA initiation
- Increase metoprolol dose
  - Limited by low blood pressure, COPD (?), depression (?)
- Add spironolactone
  - Minimal BP effect, monitor K/SCr closely (SCr 1.7 mg/dL)
Which of the following criteria does RS meet for use of ivabradine?

A. NYHA class II HFrEF  
B. Beta-blocker at max tolerated dose  
C. NSR, HR >70 bpm  
D. B and C

SHIFT: Optimization of Beta-blocker

<table>
<thead>
<tr>
<th>Main Reasons for Not Achieving Beta-blocker Target Dose</th>
<th>Main Reasons for Not Prescribing Beta-blocker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivabradine n=2099 Placebo n=2126</td>
<td>Ivabradine n=344 Placebo n=341</td>
</tr>
<tr>
<td>Hypotension</td>
<td>COPD</td>
</tr>
<tr>
<td>44%</td>
<td>37%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>Hypotension</td>
</tr>
<tr>
<td>32%</td>
<td>17%</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>Asthma</td>
</tr>
<tr>
<td>14%</td>
<td>10%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>CV decompensation</td>
</tr>
<tr>
<td>13%</td>
<td>7%</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>Dizziness/bradycardia</td>
</tr>
<tr>
<td>6%</td>
<td>7%</td>
</tr>
<tr>
<td></td>
<td>Fatigue</td>
</tr>
<tr>
<td></td>
<td>5%</td>
</tr>
</tbody>
</table>


Beta-blocker Contraindications

**Absolute contraindication:** Not recommended
- Asthma with active bronchospasm

**Relative contraindication:** Use with caution
- Diabetes with recurrent hypoglycemia
- Resting limb ischemia
- Asthma
  - Use “considerable” caution if marked bradycardia (HR <55 bpm) or marked hypotension (SBP <80 mmHg)

**No contraindication:** Appropriate to use
- COPD, diabetes, peripheral vascular disease (PVD)


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Would you add ivabradine to RS’s GDMT?

A. Yes
B. No
C. Maybe

SHIFT: Impact of HR on Outcomes

A significant treatment effect was noted only in the subgroup with baseline HR >77 bpm (median)

<table>
<thead>
<tr>
<th>Baseline Heart Rate</th>
<th>Hazard Ratio* (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>70 to &lt;72 bpm</td>
<td>1.00</td>
<td>--</td>
</tr>
<tr>
<td>72 to &lt;75 bpm</td>
<td>1.15 (0.88–1.48)</td>
<td>0.308</td>
</tr>
<tr>
<td>75 to &lt;80 bpm</td>
<td>1.33 (1.03–1.70)</td>
<td>0.027</td>
</tr>
<tr>
<td>80 to &lt;87 bpm</td>
<td>1.80 (1.40–2.31)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>≥87 bpm</td>
<td>2.34 (1.84–2.98)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

*Cardiovascular death or HF hospitalization

Would you add ivabradine to RS’s GDMT?

- Why?
  - HF+EF
  - Class III symptoms despite GDMT
  - On maximum tolerated beta blocker dose
  - Hospitalized x 2 in 6 mos
  - Cost-effective

- Why not?
  - Other options
    - Digoxin
    - Cardiac resynchronization therapy (CRT)
    - Intravenous iron
    - Left ventricular assist device (LVAD)/Transplant
    - Cost-effectiveness
### Ivabradine Cost-effectiveness in U.S.

<table>
<thead>
<tr>
<th>Population</th>
<th>Ivabradine</th>
<th>Background Therapy</th>
<th>Incremental</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Commercial Population</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitalization costs</td>
<td>$337,268</td>
<td>$375,634</td>
<td>-$38,366</td>
</tr>
<tr>
<td>AE costs</td>
<td>$5294</td>
<td>$2722</td>
<td>$2571</td>
</tr>
<tr>
<td>Drug costs</td>
<td>$27,201</td>
<td>NA</td>
<td>$27,201</td>
</tr>
<tr>
<td>Total costs</td>
<td>$369,762</td>
<td>$378,356</td>
<td>-$8594</td>
</tr>
<tr>
<td><strong>Medicare Advantage Population</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitalization costs</td>
<td>$200,032</td>
<td>$220,887</td>
<td>-$20,855</td>
</tr>
<tr>
<td>AE costs</td>
<td>$2581</td>
<td>$1325</td>
<td>$1256</td>
</tr>
<tr>
<td>Drug costs</td>
<td>$24,512</td>
<td>NA</td>
<td>$24,512</td>
</tr>
<tr>
<td>Total costs</td>
<td>$227,125</td>
<td>$222,212</td>
<td>$4913</td>
</tr>
</tbody>
</table>

Kansal AR et al. / Am Heart Assoc. 2016; May 6:5(S).

### If RS was initiated on ivabradine, what patient counseling is important?

A. Ivabradine reduces your risk of death  
B. Call if visual disturbances occur  
C. Call if COPD symptoms worsen  
D. Ivabradine does not interact with other medications

### Patient Counseling

<table>
<thead>
<tr>
<th>Medication</th>
<th>Live Longer</th>
<th>Stay Out of Hospital</th>
<th>Feel Better</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACE inhibitor</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Angiotensin receptor blocker (ARB)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Neprylisin inhibitor + ARB</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Beta-blocker</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Diuretic</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Aldosterone blocker</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Hydralazine + ISDN</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Digoxin</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Fish oil</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Ivabradine</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

UNC Healthcare Learning to Live with Heart Failure Patient Education Booklet

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Formulary Decisions

• Frequency of prescribing
• Safety
  – Sacubitril/valsartan overlap with ACE inhibitor
  – Resuming non-formulary medications upon discharge
• Cost to institution vs. cost to patient

See enlargement, p. 32
Which of these changes in your practice are you likely to make after today’s presentation?

- Compare your organization’s protocols with recently released guidelines and updates for the treatment of chronic heart failure.
- Discuss with colleagues potential changes to your protocols based on recently released guidelines and updates.
- Review your formulary for potential changes based on recently released guidelines and updates, or the introduction of new agents.
- Consider which patients might be appropriate candidates for new strategies for treating chronic heart failure.
- Devise a monitoring plan for a patient with chronic heart failure.
Specific Activity Scale Functional Class

**Walk down flight of stairs?**

- Can you do any of these without stopping?
  - Carry anything up 8 steps
  - Sexual intercourse
  - Gardening
  - Roller skate/dance
  - Walk 4 miles/hour

- Can you do any of these without stopping?
  - Carry 24 lbs up 8 steps
  - Carry objects ≥80 lbs
  - Shovel snow
  - Recreational activities/sports
  - Jog/walk 5 miles/hour

**Class III**

- Can you do any of these without stopping?
  - Shower
  - Strip/make bed
  - Mop floors
  - Hang washed clothes
  - Clean windows
  - Walk 2.5 miles/hour
  - Bowl
  - Play golf (walking)
  - Push power lawn mower

- Can you dress yourself without stopping?

**Class II**

**Class I**

**Class IV**

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**Formulary Decisions & CPOE**

*CPOE=computerized physician order entry*
Self-assessment – Patient Cases

Case 1: JA

JA is a 63 year-old African American female newly diagnosed with heart failure 2 months ago after being hospitalized for acute decompensated heart failure presents for outpatient follow-up. She reports being able to walk up & down 1 flight of stairs without symptoms but continues to have symptoms when carrying her granddaughter (~20 lbs) to her 2nd floor bedroom; she was able to do so prior to her diagnosis.

Past medical history:
- HFrEF
- Hypertension
- Diabetes mellitus
- Dyslipidemia
- Chronic kidney disease

Medications:
- Lisinopril 20 mg daily
- Carvedilol 12.5 mg twice daily
- Bumetanide 1 mg twice daily
- Atorvastatin 80 mg daily
- Insulin glargine 20 units daily

Vital signs:
- Blood pressure 116/78 mmHg
- Heart rate 54 bpm
- Respiratory rate 16 bpm
- Oxygen saturation 99% on RA

Transthoracic echocardiogram (2 months prior):
- Left ventricular ejection fraction 25%

Laboratories:
- Sodium: 134 mEq/L
- Potassium: 4.3 mEq/L
- Creatinine: 2.3 mg/dL
- Estimated GFR: ~25 mL/min/1.73m²

Insurance:
- PPO through employer

Questions to consider:

What functional class is this patient?

Is this patient on optimal guideline-directed medical therapy?

What, if any, changes would you recommend?

Is this patient a candidate for sacubitril/valsartan?

What, if any, concerns would you have about initiating sacubitril/valsartan?

If sacubitril/valsartan were started, what is your plan for initiation, titration, monitoring and counseling?
Case 2: RS

RS is a 65 year-old Caucasian male who is referred from the local community hospital for advanced therapy work-up. He was diagnosed with HFrEF 2 years ago and has had two HF hospitalizations within the past 6 months. Since his diagnosis, RS has experienced a progressive decline in his functional status. He previously walked his dog approximately 1 mile daily, he know experiences DOE and fatigue with retrieving his mail and grocery shopping. He has no SOB at rest. He does admit to reduced mood given ADL limitations.

Past medical history:
HFrEF
IDCM, ICD in 2015
COPD
Smoking

Medications:
Furosemide 40 mg twice daily
Enalapril 2.5 mg twice daily
Metoprolol XL 50 mg daily
Fluticasone/salmeterol 500 mcg/50 mcg BID
Tiotropium 18 mcg daily
Varenicline 1 mg twice daily

Vital signs:
Blood pressure 92/58 mmHg
Heart rate 95 bpm
Respiratory rate 14 bpm
Oxygen saturation 97% on RA

Height: 70 inches
Weight: 82 kg

Transthoracic echocardiogram: LVEF 20-25% (8/2016), LVEF 30-35% (7/2014)

Laboratories:
Sodium: 127 mEq/L
Potassium: 4.7 mEq/L
Creatinine: 1.7 mg/dL
Estimated GFR: ~60 mL/min/1.73m2

Insurance: Medicare Advantage

Questions to consider:
What functional class is this patient?

Is this patient on optimal guideline-directed medical therapy?

What, if any, changes would you recommend?

Is this patient a candidate for ivabradine? Why or why not?

What, if any, concerns would you have about initiating ivabradine?

If ivabradine was started, what is your plan for initiation, titration, monitoring and counseling?
New and Emerging Strategies for the Treatment of Chronic Heart Failure:
A Clinical Case Studies Workshop

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2. Click on Process CE for the Midyear Clinical Meeting and Exhibition.
3. Enter the attendance code announced during the session and click submit.
4. Click Claim for any session.
5. Complete the evaluation.
6. Once all requirements are complete (indicated with a green check mark), click Claim Credit.
7. Review the information for the credit you are claiming. If all information is correct, check the box at the bottom and click Claim. You will see a message if there are any problems claiming your credit.

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2. Enter the enrollment code announced during the webinar in the Enrollment Code box and click Redeem. The title of this activity will appear in a pop-up box on your screen. Click on Go or the activity title.
3. Complete all required elements. Go to step six above.

| Activity Date: | Monday, December 5, 2016 | Code: | _ _ _ _ _ _ | CE Hours: | 1.5 |

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