Evidence-Based Beta Blockers

Southwest Affiliate Webinar
January 27, 2014
Larry Allen, MD – U of Colorado

heart.org/getwiththeguidelines
• I will **not** discuss off label use or investigational use in my presentation.

• **I have** financial relationships to disclose:
  
  – Employee of: **University of Colorado** (>$10,000)
  
  – Consultant for: **J&J / Janssen, Novartis, Amgen** (<$5,000)
  
  – Stockholder in: None
  
  – Research support from: **NIH / NHLBI, AHA** (>$10,000)
  
  – Honoraria from: None

• *I do not have all the answers.*
Summary

• Why BB? Patients
  – EBM for HFREF
  – BB data, including COMET

• Why BB? Providers/Hospitals
  – Public reporting and VBP

• What Can We Do?
  – Practical Considerations on BB
  – CU experience and IT options
GWTG HF Achievement Measures

* Modified to include Beta Blocker at Discharge and Discharge Instructions rather than Evidence-Based Beta Blocker at D/C and Post Discharge Appointment

Baseline = Admissions Jan2005 – Dec2005
April 2013
Current = Overall
Some “light” reading – 3 guidelines

• 2013 ACCF/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults
  – http://circ.ahajournals.org/content/128/16/e240.full.pdf+html

• 2012 ESC Guidelines for the Diagnosis and Treatment of Acute and Chronic Heart Failure

• 2010 HFSA Practice Guideline
  – http://www.heartfailureguideline.org
HFrEF Stage C  
NYHA Class I – IV  
Treatment:

- **Class I, LOE A**
  - ACEI or ARB AND Beta Blocker

For all volume overload, NYHA class II-IV patients:
- Add
  - **Class I, LOE C**
    - Loop Diuretics

For persistently symptomatic African Americans, NYHA class III-IV:
- Add
  - **Class I, LOE A**
    - Hydral-Nitrates

For NYHA class II-IV patients, provided estimated creatinine >30 mL/min and K+ <5.0 mEq/dL:
- Add
  - **Class I, LOE A**
    - Aldosterone Antagonist

GDHT
## Medical Therapy for Stage C HFrEF: Magnitude of Benefit Demonstrated in RCTs

<table>
<thead>
<tr>
<th>GDMT</th>
<th>RR Reduction in Mortality</th>
<th>NNT for Mortality Reduction (Standardized to 36 mo)</th>
<th>RR Reduction in HF Hospitalizations</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACE inhibitor or ARB</td>
<td>17%</td>
<td>26</td>
<td>31%</td>
</tr>
<tr>
<td>Beta blocker</td>
<td>34%</td>
<td>9</td>
<td>41%</td>
</tr>
<tr>
<td>Aldosterone antagonist</td>
<td>30%</td>
<td>6</td>
<td>35%</td>
</tr>
<tr>
<td>Hydralazine/nitrate</td>
<td>43%</td>
<td>7</td>
<td>33%</td>
</tr>
</tbody>
</table>
Effect of β-Blockade on All-Cause Mortality by Etiology and NYHA Class

NYHA II

NYHA III

NYHA IV

Ischemic

Nonischemic

Relative Risk and 95% Confidence Intervals

* Not a planned endpoint.
Effect of β-Blockade on All-Cause Mortality by Etiology and NYHA Class

- NYHA II
- NYHA III
- NYHA IV

Ischemic
Nonischemic

Relative Risk and 95% Confidence Intervals

CIBIS-II  MERIT-HF  US CARV TRIALS*

* Not a planned endpoint.
Effect of β-Blockade on All-Cause Mortality by Etiology and NYHA Class

Relative Risk and 95% Confidence Intervals

* Not a planned endpoint.
Effect of β-Blockade on All-Cause Mortality by Etiology and NYHA Class

Relative Risk and 95% Confidence Intervals

- NYHA II
- NYHA III
- NYHA IV
- Ischemic
- Nonischemic

* Not a planned endpoint.
Why not all BB?

- Carvedilol
- Metoprolol succinate
- Bisoprolol

- Metoprolol tartrate (Lopressor)
- Nabivolol
- Bucindolol
Comparison of carvedilol and metoprolol on clinical outcomes in patients with chronic heart failure in the Carvedilol Or Metoprolol European Trial (COMET): randomised controlled trial

Philip A Poole-Wilson, Karl Swedberg, John G F Cleland, Andrea Di Lenarda, Peter Hanrath, Michel Komajda, Jacobus Lubsen, Beatrix Lutiger, Marco Metra, Willem J Remme, Christian Torp-Pedersen, Armin Scherhag, Allan Skene, for the COMET investigators*
COMET: Effect Carvedilol vs Metoprolol Tartrate on Mortality in HF

Risk Reduction
\[ \downarrow 17\% \]
(7%, 26%)
\[ P=0.0017 \]

Mortality rates: metoprolol 40%; Carvedilol 34%.

Extrapolation from the survival curves suggested that carvedilol extended median survival by 1.4 years as compared with metoprolol tartrate †

Metoprolol tartrate mean dose: 85 mg QD; Carvedilol mean dose: 42 mg QD.
COMET did not evaluate metoprolol succinate, the agent used in the MERIT-HF Trial

Not All β-Blockers Reduce Mortality Equally in HF

**BEST**

Risk Reduction ↓ 10%
(-2%, 22%)

Survival (%)

- Bucindolol (n=1,354)
- Placebo (n=1,354)

Follow-Up (months)

\[ P = .105 \]

2,708 patients (CHF Class III–IV, average age 60, LVEF .23) randomized to placebo or bucindolol (3 mg titrated to 50 mg po BID).

Number of events: bucindolol 411 (30%); placebo 449 (33%).

**SENIORS**

Risk Reduction ↓ 12%
(-8%, 29%)

Survival (%)

- Nebivolol (n=1,067)
- Placebo (n=1,061)

Time (months)

\[ P = .214 \]

2,128 patients (CHF Class II–III, average age 76, average LVEF .36 with approximately 65% of patients with LVEF ≤.35) randomized to Placebo or nebivolol (1.25 mg titrated to 10 mg po QD). All-cause mortality was a secondary endpoint.

Number of events: nebivolol 169 (15.8%); placebo 192 (18.1%).

\[ ^1 \text{BEST Investigators. } N \text{Engl J Med. 2001;344:1659-1667.} \]
7.3.2.4. Beta Blockers: Recommendation

Class I

1. Use of 1 of the 3 beta blockers proven to reduce mortality (eg, bisoprolol, carvedilol, and sustained-release metoprolol succinate) is recommended for all patients with current or prior symptoms of HFrEF, unless contraindicated, to reduce morbidity and mortality.\(^\text{346,416–419,448}\) (Level of Evidence: A)
# BB Options and Dosing

## Table 15. Drugs Commonly Used for Stage C HFrEF

<table>
<thead>
<tr>
<th>Drug</th>
<th>Initial Daily Dose(s)</th>
<th>Maximum Dose(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Beta blockers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bisoprolol</td>
<td>1.25 mg once</td>
<td>10 mg once</td>
</tr>
<tr>
<td>Carvedilol</td>
<td>3.125 mg twice</td>
<td>50 mg twice</td>
</tr>
<tr>
<td>Carvedilol CR</td>
<td>10 mg once</td>
<td>80 mg once</td>
</tr>
<tr>
<td>Metoprolol succinate extended release (metoprolol CR/XL)</td>
<td>12.5 to 25 mg once</td>
<td>200 mg once</td>
</tr>
</tbody>
</table>

## Mean Doses Achieved in Clinical Trials

<table>
<thead>
<tr>
<th>Drug</th>
<th>Mean Dose Achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Beta blockers</strong></td>
<td></td>
</tr>
<tr>
<td>Bisoprolol</td>
<td>8.6 mg/d[^117]</td>
</tr>
<tr>
<td>Carvedilol</td>
<td>37 mg/d[^447]</td>
</tr>
<tr>
<td>Carvedilol CR</td>
<td>N/A</td>
</tr>
<tr>
<td>Metoprolol succinate extended release (metoprolol CR/XL)</td>
<td>159 mg/d[^448]</td>
</tr>
</tbody>
</table>
Caveats
Heart Failure Types

<table>
<thead>
<tr>
<th>Chronic (Stable)</th>
<th>HFrEF (LVEF &lt; 40%)</th>
<th>HFpEF (LVEF &gt; 50%)</th>
<th>RV Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute (Unstable)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Rx on HF 1) acuity 2) type 3) severity

<table>
<thead>
<tr>
<th></th>
<th>HFrEF (LVEF &lt; 40%)</th>
<th>HFpEF (LVEF &gt; 50%)</th>
<th>RV Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Stable)</td>
<td>GDMT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Unstable)</td>
<td>?</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>
Effects / side effects

1. Bronchoconstriction (rare, use β1 selective for COPD/RAD)
2. Fatigue (1.8%, P>0.05)
3. Sexual dysfunction (0.5%, P>0.05)
4. Depression (no increase)
5. Acute negative inotrope/chronotrope

Table 3. Fatigue in Active Treatment and Placebo Groups in Randomized Trials of β-Blockers

<table>
<thead>
<tr>
<th>Source</th>
<th>Reported Symptoms, Events/No. Randomized (%)</th>
<th>Withdrawals, Events/No. Randomized (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Active Treatment</td>
<td>Placebo</td>
</tr>
<tr>
<td>Norwegian Multicenter Group, 11 1981</td>
<td>45/405 (4.8)</td>
<td>11/399 (1.2)</td>
</tr>
<tr>
<td>Taylor et al, 12 1982</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Hansteen et al, 13 1982</td>
<td>38/278 (13.7)</td>
<td>19/282 (6.7)</td>
</tr>
<tr>
<td>BHAT, 14 1982</td>
<td>1280/1916 (66.8)</td>
<td>1193/1921 (62.1)</td>
</tr>
<tr>
<td>Julian et al, 15 1982</td>
<td>367/873 (42.0)</td>
<td>216/538 (37.0)</td>
</tr>
<tr>
<td>Olsson et al, 16 1985</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>MRC-mild hypertension, 17 1985</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Coope and Warrender, 18 1986</td>
<td>167/348 (48.0)</td>
<td>173/377 (46.0)</td>
</tr>
<tr>
<td>STOP-hypertension, 19 1991</td>
<td>133/552 (24.1)</td>
<td>122/563 (21.7)</td>
</tr>
<tr>
<td>MRC-older adults, 22 1992</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Perez-Stable et al, 26 1995</td>
<td>55/156 (35.0)</td>
<td>36/156 (23.0)</td>
</tr>
<tr>
<td>US Carvedilol Heart Failure Study, 27 1996</td>
<td>177/696 (25.4)</td>
<td>93/398 (23.4)</td>
</tr>
<tr>
<td>MERIT-HF, 28 1999</td>
<td>20/1900 (1.0)</td>
<td>14/2001 (0.7)</td>
</tr>
<tr>
<td>BEST, 29 2001</td>
<td>756/1354 (55.8)</td>
<td>733/1354 (54.1)</td>
</tr>
<tr>
<td>Total</td>
<td>3038/3108 (33.4)</td>
<td>2610/8574 (30.4)</td>
</tr>
</tbody>
</table>

Ko et al. JAMA 2002;288;351.
Beta-Agonism v. Antagonism: CHRONIC
Beta-Agonism v. Antagonism: ACUTE
Beta Blocker Therapy in Heart Failure

Contraindications:

- Cardiogenic shock (pet peeve: dobutamine + BB)
- Severe reactive airway disease (this is not all COPD)
- 2/3rd degree HB (without BiV pacing)

Start at very low HF doses and up-titrate to target doses at two week intervals, or highest dose short of target dose that is well tolerated

Monitor HR and BP and symptoms
HF is not exactly 2 diseases

De Keulenaer GW, Brutsaert DL. Circ 2009;119:3044
## Table 3. Definitions of HFrEF and HFpEF

<table>
<thead>
<tr>
<th>Classification</th>
<th>EF (%)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Heart failure with reduced ejection fraction</td>
<td>≤40</td>
<td>Also referred to as systolic HF. Randomized controlled trials have mainly enrolled patients with HFrEF, and it is only in these patients that efficacious therapies have been demonstrated to date.</td>
</tr>
<tr>
<td>(HFrEF)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>II. Heart failure with preserved ejection fraction</td>
<td>≥50</td>
<td>Also referred to as diastolic HF. Several different criteria have been used to further define HFpEF. The diagnosis of HFpEF is challenging because it is largely one of excluding other potential noncardiac causes of symptoms suggestive of HF. To date, efficacious therapies have not been identified.</td>
</tr>
<tr>
<td>(HFpEF)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. HFpEF, borderline</td>
<td>41 to 49</td>
<td>These patients fall into a borderline or intermediate group. Their characteristics, treatment patterns, and outcomes appear similar to those of patients with HFpEF.</td>
</tr>
<tr>
<td>b. HFpEF, improved</td>
<td>&gt;40</td>
<td>It has been recognized that a subset of patients with HFpEF previously had HFrEF. These patients with improvement or recovery in EF may be clinically distinct from those with persistently preserved or reduced EF. Further research is needed to better characterize these patients.</td>
</tr>
</tbody>
</table>
# The Beta-Blocker Measure

- **ACCF/AHA/AMA-PCPI 2011 HF Performance Measurement Set**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Description*</th>
<th>Care Setting</th>
<th>Level of Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Beta-blocker therapy for LVSD (outpatient and inpatient setting)</td>
<td>Percentage of patients aged ≥18 y with a diagnosis of HF with a current or prior LVEF &lt;40% who were prescribed beta-blocker therapy with bisoprolol, carvedilol, or sustained release metoprolol succinate either within a 12 mo period when seen in the outpatient setting or at hospital discharge</td>
<td>Inpatient and Outpatient</td>
<td>Individual practitioner Facility</td>
</tr>
</tbody>
</table>
Added acceptable contraindications to Evidenced Based Beta Blockers:

- It is extremely unlikely that all three evidenced beta blockers would not be tolerated in a patient, but a non-evidenced based beta blocker would be tolerated. This scenario is so rare that there is not a need to separate contraindications by beta blocker class (evidenced based and non-evidence based).

- In the extremely rare instance all three evidenced based beta blockers are contraindicated in the patient, you can select “Yes”, if the contraindication is documented by a physician, APN or PA and expressly references all three beta blocker medications e.g. “No - Bisprolol, Coreg or Toprol XL - all not tolerated” or reference to the contraindication specifically states that as a class “evidenced based beta blockers” are contraindicated (e.g. “evidenced based beta blockers all tried previously, patient is intolerant to all”) . This should almost never occur.
Added **unacceptable contraindications** to Evidenced Based Beta Blockers:

- **Cost is NOT an acceptable reason** for not prescribing an evidenced based beta blocker at hospital discharge.

- **Heart Failure patients with reduced EF** may come into the hospital on non-evidenced-based beta blocker therapy that is well tolerated. This is **NOT an acceptable reason** for not prescribing an evidenced based beta blocker at discharge. The positive findings in the three evidenced based beta blockers are not indicative of a beta blocker class effect and are specific to these three medications.
CHALLENGES

I Expected Times Like This- but Never Thought They’d Be So Bad, So Long, and So Frequent.
LIMITATIONS

UNTIL YOU SPREAD YOUR WINGS,
YOU’LL HAVE NO IDEA HOW FAR YOU CAN WALK.
Beta-Blockers: A practical view

Not all are BB are created equal

1. Carvedilol  
   - β1:β2: 1:1 (plus α1)  
   - Dosing: bid  
   - Cost: $4/mo

2. Metoprolol succinate ER  
   - β1:β2: 30:1  
   - Dosing: daily/bid  
   - Cost: more

3. Bisoprolol  
   - β1:β2: 130:1  
   - Dosing: daily  
   - Cost: $?$/4

The heart rate did not differ after 16 months. At 4 months, patients mean decrease of systolic blood pressure from baseline was 3.8 mm Hg (SD 17.4) in the carvedilol group and 2.0 mm Hg (SD 17.7) in the metoprolol group (difference -1.8 mm Hg, 95% CI -3.2 to -0.4).

Lancet 2003; 362: 7–13
Table 20. Strategies for Achieving Optimal GDMT

1. **Uptitrate in small increments** to the recommended target dose or the highest tolerated dose for those medications listed in Table 15 with an appreciation that some patients cannot tolerate the full recommended doses of all medications, particularly patients with low baseline heart rate or blood pressure or with a tendency to postural symptoms.

2. Certain patients (e.g., the elderly, patients with chronic kidney disease) may require **more frequent visits and laboratory monitoring during dose titration** and more gradual dose changes. However, such vulnerable patients may accrue considerable benefits from GDMT. Inability to tolerate optimal doses of GDMT may change after disease-modifying interventions such as CRT.

3. **Monitor vital signs closely** before and during uptitration, including postural changes in blood pressure or heart rate, particularly in patients with orthostatic symptoms, bradycardia, and/or “low” systolic blood pressure (e.g., 80 to 100 mm Hg).

4. **Alternate adjustments of different medication classes** (especially ACE inhibitors/ARBs and beta blockers) listed in Table 15. Patients with elevated or normal blood pressure and heart rate may tolerate faster incremental increases in dosages.

5. **Monitor renal function and electrolytes** for rising creatinine and hyperkalemia, recognizing that an initial rise in creatinine may be expected and does not necessarily require discontinuation of therapy; discuss tolerable levels of creatinine above baseline with a nephrologist if necessary.

6. Patients may complain of **symptoms of fatigue and weakness** with dosage increases; in the absence of instability in vital signs, reassure them that these symptoms are often transient and usually resolve within a few days of these changes in therapy.

7. **Discourage sudden spontaneous discontinuation of GDMT medications** by the patient and/or other clinicians without discussion with managing clinicians.

8. Carefully review doses of other medications for HF symptom control (e.g., diuretics, nitrates) during uptitration.

9. **Consider temporary adjustments in dosages of GDMT** during acute episodes of noncardiac illnesses (e.g., respiratory infections, risk of dehydration, etc).

10. **Educate patients, family members, and other clinicians** about the expected benefits of achieving GDMT, including an understanding of the potential benefits of myocardial reverse remodeling, increased survival, and improved functional status and HRQOL.
Predischarge Initiation of Carvedilol in Patients Hospitalized for Decompensated Heart Failure
Results of the Initiation Management Predischarge: Process for Assessment of Carvedilol Therapy in Heart Failure (IMPACT-HF) Trial

Wendy A. Gattis, PharmD,* Christopher M. O’Connor, MD, FACC,* Dianne S. Gallup, MS,*

At 60 days 165 patients (91.2%) randomized to predischarge carvedilol initiation were treated with a beta-blocker, compared with 130 patients (73.4%) randomized to initiation postdischarge (p < 0.0001). Predischarge initiation was not associated with an increased risk of serious adverse events. The median length of stay was five days in both groups.

Allen et al. BMC Cardiovascular Disorders 2012, 12:43

Table 2 Absolute and exposure rates to β-blocker intensification for case and control 30- day time periods, with adjusted odds ratios for exposure

<table>
<thead>
<tr>
<th>Proportion with β-blocker intensification in preceding 30-day window</th>
<th>Adjusted OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>CASE (n = 1674)</td>
<td>CONTROL (n = 1674)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2.33% (n = 39)</td>
<td>1.61% (n = 27)</td>
</tr>
<tr>
<td>LVSD</td>
<td>2.44% (n = 14)</td>
<td>2.26% (n = 13)</td>
</tr>
</tbody>
</table>
Systems
Leverage EMR (Epic)
Patient Identification

• Identification algorithm:

  1. Heart failure ICD-9 codes from problem list, OR

  2. BNP >150 pg/ml, OR

  3. IV loop diuretic during current encounter

• A BPA appears to the admitting or discharging provider and suggests use of the heart failure specific order set
BestPractice Advisories

Critical (1 Advisory)

Please use the Heart Failure Admission Order Set in patients with suspected/actual heart failure. (BPA# 922)

Acknowledge reason:
- Doesn't have HF - don't use HF order set
- Defer decision re: HF admit order set

☑️ Open Order Set: UCH Congestive Heart Failure Admission preview

Last refreshed on 9/25/2013 at 8:26 AM

---

Please use the Heart Failure Discharge Order Set in patients with suspected/actual heart failure. (BPA# 927)

Acknowledge reason:
- Doesn't have HF - don't use HF order set
- Defer decision re: HF discharge order set
- I will place orderset
- Already ordered

☑️ Open Order Set: UCH Congestive Heart Failure Discharge preview

The following actions were applied automatically:
☑️ Message sent: This advisory has been sent via In Basket
Automated real-time HF ID

From 8/1/2013 – 9/15/2013:

• 36 with primary discharge diagnosis of HF
• 221 with any discharge diagnosis of HF
  – Correctly identified 35/36 (97.2%) patients at admission who had final PRIMARY discharge diagnosis of heart failure
  – Correctly identified 164/221 (74.2%) of patients who had ANY discharge diagnosis of heart failure
Leverage EMR - Orders

ACEI/ARB Core Measure — Required
These are required data elements for Core Measure reporting.
If LVEF less than 40%, an ACEI OR ARB prescription at discharge is indicated, UNLESS a valid contraindication is provided.

- ACEI/ARB not specifically indicated for heart failure; LVEF greater than or equal to 40%
- ACEI/ARB contraindicated at discharge
- ACEI prescribed
- ARB prescribed

Follow-Up
It is recommended that patients admitted with a heart failure exacerbation should be seen by a provider within SEVEN DAYS of discharge.

☑ Follow-Up has been scheduled.

Name: ***, Date: ***, Time: ***, Location: ***, Phone #: ***.

Additional Order Details

It is very important for you to make and keep the follow-up appointment listed. It is generally recommended that you follow up with a health care provider (e.g., your doctor) within 7 days of hospital discharge following a heart failure exacerbation. We have made an appointment for you:

Name: ***, Date: ***, Time: ***, Location: ***, Phone #: ***.
Leverage EMR (Epic): Contraindications / Teaching

ACEI/ARB Core Measure — Required
These are required data elements for Core Measure reporting. If LVEF less than 40%, an ACEI OR ARB prescription at discharge is indicated, UNLESS a valid contraindication is provided.

- ACEI/ARB not specifically indicated for heart failure; LVEF greater than or equal to 40%
- ACEI/ARB contraindicated at discharge
- ACEI prescribed
- ARB prescribed

Scheduled Times: Hide Schedule
10/18/13 1536
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www.heart.org/swaquality