Non-Pharmacologic Management: Impact of Lifestyle and Comorbidities

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Presenter Disclosure Information
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I will discuss investigational use of adaptive servoventilation.

I have no financial relationships to disclose.

Non-Pharmacologic Approach

Co-Morbidities
- COPD
- HTN
- DM
- Renal
- Inactivity
- Weight

Non-pharmacologic Approach
- Sleep disordered breathing
- Depression
- Cognitive problems
- Social Co-morbidities
- Sodium/Fluid Restriction
- Assisted ventilation
- Activity – traditional and non-traditional types
- Multidisciplinary team (Self-care education, social support, frailty)

Guidelines: ACCF/AHA

Sodium & Fluid Restriction
- Stage A & B Heart Failure
  - Sodium intake 1.5 g/d – appropriate for most patients because of the association between sodium consumption and hypertension, LV hypertrophy, and cardiovascular disease
- Stage C & D Heart Failure
  - Insufficient data to recommend any specific level of sodium intake. “Consider some degree...<3g for symptom improvement.”
  - Patient Education: sodium restriction is reasonable especially in symptomatic HF to reduce congestive symptoms.
  - (Level of Evidence: C)

HFpEF

- Fewer data
- In clinical practice - assumption that excess sodium is associated with fluid retention and hospitalization
- Excess sodium restriction is associated with worsening neuro-hormonal response


Sodium Restriction in Stable HF

- 12 week prospective RCT, N=97, NYHA class II-IV
- Medically optimized, previous signs of fluid retention on either > 40mg furosemide (NYHA III-IV) or >80mg (NYHA II-IV)
- Randomized to either Na 2-3g/d & fluid 1.5L/d (individualized sodium restriction) or usual nurse-led HF information
- Composite primary endpoint: NYHA functional class, hospitalization, weight, peripheral edema, quality of life, thirst, and diuretic use


Heart Failure Adherence and Retention Trial (HART)

- N=902 (833 had Na data) 2001-04, NYHA class II-III, followed over median 36 months
- Compared self-management counseling versus education alone
- 18, 2 hour group meetings with 10 pts over 1 year using Tipsheets endorsed by AHA
- Propensity scoring was used to match pts for disease severity, diuretic use, EF, co-morbid, medical therapy.
- Sodium restricted group defined as <2500mg/d vs >2500mg/d
- Endpoint: death or HF hospitalization

Doukky et al, J Am Coll Cardiol HF 2016;4:24–35
Heart Failure Adherence and Retention Trial (HART)

- Sodium restriction associated with the risk of death or HF hospitalization (42.3% vs. 26.2%; hazard ratio 1.85)
- Non-significant increase in the rate of cardiac death


Sodium & Fluid Restriction ADHF

Examined:
- Weight loss
- Clinical stability
- Thirst perception
- Readmissions


Aggressive Fluid and Sodium Restriction in Acute Decompensated Heart Failure: A Randomized Clinical Trial

No effect on wt, stability, increased Thirst in intervention group


Table 3. Clinical and Laboratory Variables at 30-day follow-up

Sleep Disordered Breathing Guidelines: ACCF/AHA

- Continuous positive airway pressure can be beneficial to increase LVEF and improve functional status in pts with HF and sleep apnea

(Level of Evidence: B)


Positive Airway Pressure Therapy Features

<table>
<thead>
<tr>
<th>Feature</th>
<th>CPAP</th>
<th>BiPAP</th>
<th>Bi-level APAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure Profile</td>
<td>Maintain upper airway open</td>
<td>Continuously adjusting inspiratory and expiratory pressure</td>
<td>Maintain upper airway open</td>
</tr>
</tbody>
</table>


Canadian Trial of CPAP Treatment in Patients With Chronic Heart Failure & Central Sleep Apnea - CANPAP

- 258 patients with HF + CSA, age=63, LVEF 25, NYHA II (67%) or III/IV (33%)
- Randomly assigned to CPAP or no CPAP and followed for mean of 2 years
- Endpoints: sleep, EF, exercise capacity, QOL, neurohormones, survival

Bradley et al. NEJM 2005;353 (19): 2025-33

CPAP in Central Sleep Apnea

Cpap improved CSA, norepinephrine levels, oxygenation, EF, and increased 6MWT distance but did not affect QOL, no diff in survival between groups

Bradley et al. NEJM 2005;353 (19): 2025-33
**Adaptive Servo-Ventilation**

Positive airway pressure ventilation that continuously monitors the patient's breathing pattern using an algorithm.

- Designed to detect episodes of sleep apnea and intervene to maintain breathing at 90% of what had been normal for that individual just prior to episode.

Inspiratory pressure on top of expiratory positive airway pressure.

American Sleep Association:  
[https://www.sleepassociation.org/adaptive-servo-ventilation](https://www.sleepassociation.org/adaptive-servo-ventilation)

**Adaptive Servo-Ventilation for Central Sleep Apnea in HFrEF - SERVE-HF**

- 1325 patients with HFrEF + Central Sleep Apnea, AHI 15 or more/hr
- ASV vs guideline med tx (control)
  - Age 69 yrs, NYHA II (30%), III or IV (70%), BMI 28.5
  - Any-cause death or life-saving cardiovascular intervention (txp, vad, shock, hosp)


**CAT- HR Trial**

- Prospective, RCT, SDB (CSA or OSA) + ADHF
- Used adaptive servo-ventilation
- HFrEF OR HFpEF
- N=215 expected enrollment
- Endpoint death, CV hospitalization, 6MWD
- All-cause and CV mort were ASV group
- Stopped early (N=126) due to safety concerns for pts with HFrEF (LVEF<45%)

Fiuzat et al. Contemp Clin Trials 2016;47:158-64
Ongoing Trial with ASV

- ADVENT HF
  - CSA or OSA + CHF
  - AHA Stage B-D, LVEF < 45%
  - 860 patients; Europe, N. America
  - Endpoint-driven with expected minimum 2 year f/u
  - All cause death or HF hospitalization
  - Still enrolling

- Results expected 2016

Obesity: Guidelines?

ACCF/AHA (2013)
No specific recommendation

The Obesity Paradox in Heart Failure

Obese people are more likely to develop heart failure
Obese people with heart failure live longer than normal or underweight people

Bariatric Surgery in HF

<table>
<thead>
<tr>
<th>Condition</th>
<th>% (% with each comorbidity)</th>
<th>% Death within 30 days</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>11,922 (59.0%)</td>
<td>2.2%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>15,291 (43.0%)</td>
<td>4.6%</td>
<td>0.03%</td>
</tr>
<tr>
<td>Acute Heart Failure</td>
<td>11,922 (59.0%)</td>
<td>1.4%</td>
<td>0.091</td>
</tr>
</tbody>
</table>

The presence of CHF increases the operative mortality risk from bariatric surgery 7-fold

Horwich TB, et al. JACC 2001;38:788-95
Exercise Training in Heart Failure Guidelines ACCF/AHA

- **Class I**
  Exercise training (or regular physical activity) is recommended as safe and effective for patients with HF who are able to participate to improve functional status. (Level of Evidence: A)

- **Class IIa**
  Cardiac rehabilitation can be useful in clinically stable patients with HF to improve functional capacity, exercise duration, HRQOL, and mortality. (Level of Evidence: B)


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**Efficacy and Safety of Exercise Training in Patients With Chronic Heart Failure:**

**HF-ACTION Randomized Controlled Trial**

N=2331, mean EF 25%, 3 months of exercise vs usual care

- **Efficacy:**
  - Modest significant reductions for both all-cause mortality or hospitalization and cardiovascular mortality or heart failure hospitalization

- **Safety:**
  - Increased LVEF (36%), NT pro-BNP

**Yoga in Heart Failure**

- **Pullen (2010)** – N=40 AA 12-weeks of yoga
  - Improved peak VO2, QoL, inflammatory markers, and flexibility
- **Howie-Esquivel (2010)** – N=12 Modified Yoga in HF
  - Increased QOL, 6MWT, muscle strength
- **Selman (2015)** – N=15 Tele-yoga in HF and COPD pts participated in yoga viewed at home
  - Less social isolation and high enjoyment of the yoga
- **Gomes-Neto (2014)** - “Meta-Analysis” 2 studies (N=59), effects of yoga on exercise capacity and QOL
  - Improved peak VO2 and QOL
- **Krishna (2014)** – N=92 RCT over 12 weeks
  - Increased LVEF (36%), NT pro-BNP
Tai Chi in Heart Failure

- Meta-analysis of 4 RCTs
- Evaluated Tai Chi vs usual care
- LVEF<45%, N=242
- Tai Chi significantly improved QOL
- Not associated with decreased:
  - NT pro-BNP
  - SBP
  - 6MWD
  - Peak VO2


Patient Education in Heart Failure

- ACCF/AHA Guidelines recommend self-care management i.e. patient education.
  (Level of evidence B)
- Systematic review of 35 patient education studies improved knowledge, self-monitoring, med adherence, re-hospitalization and days in hospital.
- Caution regarding cultural considerations of “self-care” not always valued in various cultures – patient/family engagement may be more effective.
- Caution regarding best method of pt. teaching – no data to support (Teach-back vs other methods, cognitive status)


Social Co-Morbidities in Heart Failure

- Social Support – Guidelines recommend, but no specific information
  N=333, mean age 72, NYHA III, categorized pts in low, mod and high levels of social support
  ->Pts with high levels of social support had sig better self-care (p=.002)
- Social Support and Partner Status
  N=809, mean age 68, 261 reported a partner
  -> non-partnered 1.8 times greater risk for readmission (p=.01)
- Frailty Assessment?
  N=40, >65 LVEF <35%, NYHA class III/IV (Fried Frailty Index)
  ->Association with all-cause hospitalization (p=.017) but not HF hosp


Multi-disciplinary Care HF Guidelines: ACCF/AHA

- Class 1
  Recommended that patients with heart failure are enrolled in a multidisciplinary-care management programm to reduce the risk of heart failure hospitalization.
  (Level of Evidence A)


Adjusted HR – 0.97 (95% CI 0.73 to 1.30), p = 0.861
(Age, sex, cardiac function, clinical profile & site)

Event-free survival

Multidisciplinary Programs

Problems with MD Programs

Despite high level evidence to support MD programs
- Less evidence regarding individual program components
- No specific program content identified
- Best manner of delivery
- Health care system, patient factors and provider factors influence effectiveness of all programs

Non-Pharmacologic Approach

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- Sleep disordered

Non-pharmacologic Approach
- Diet – Sodium/Fluid Restriction ??
- Assisted ventilation Cpap yes OSA, ASV and/or CSA no/??
- Activity = traditional and non-traditional types YES
- Multidisciplinary team (Self-care education +, social support +, Frailty ?) YES