Inotropic Therapy: Key Considerations for Home-Based Heart Failure Patients

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Top 4 Things to Know for CE

1. Make sure your BADGE IS SCANNED each time you enter a session to record your attendance.

2. Carry your Evaluation Packet with you to EVERY session.

3. Pharmacists, Pharmacy Technicians and Nurses need to track their hours on the Statement of Continuing Education Form as they go (the 2-page triplicate form, so press firmly!).

4. FOR CE: At your last session, total the hours and sign both pages of your Statement of Continuing Education Form.
   - Keep the PINK copy for your records and place the YELLOW and WHITE copies in your CE Envelope.
   - Make sure an Evaluation Form is in your CE Envelope for each session you attended (extra forms are available at the registration desk if you forgot to pick one up).
   - Write your name and unique ID number (six digit number at the bottom of your name badge) in the designated area on the outside of the envelope, seal it, and place it in the drop box located near the registration area.
• Felicia Schaps declares no conflicts of interest or financial interest in any service or product mentioned in this program.

• Clinical trials and off-label/investigational uses may be discussed but in a fair and unbiased manner.
Objectives

At the conclusion of this program the learner will be able to:

• Explain the purpose and action of inotropic therapy and identify commonly used drugs

• Define patient selection criteria for home administration of inotropic therapy.

Privileged and Confidential
Objectives Continued

• List the key clinical monitoring considerations for the patient receiving inotropic therapy

• Explain the primary goals of inotropic therapy

• Describe reimbursement guidelines and Medicare coverage criteria for inotropic therapy
Overview

• Approximately 5 million people in the US suffer from congestive heart failure

• Cardiac transplant is currently available to no more than 2,500 people in the US a year

• CHF is a condition in which the heart can no longer pump enough blood to meet the body’s needs

• Decreased pumping causes fluid build up in major organs

• Pediatric failure is generally related to genetic defects and Duchenne Muscular Dystrophy
Congestive Heart Failure
Causes

- Narrowing of blood vessels
- Cardiomyopathy
- Alcoholism and cocaine use
- Chemotherapy drugs
- End-stage kidney disease
- High blood pressure
- Emphysema
- Hyper or hypothyroidism
Symptoms

• Shortness of breath with activity
• Cough
• Swelling of feet and ankles
• Swelling of abdomen
• Weight gain
• Early satiety or indigestion
• Fatigue, weakness, faintness
• Difficulty sleeping
Symptoms of CHF

- Coughing
- Tiredness
- Shortness of breath
- Pulmonary edema (excess fluid in lungs)
- Pumping action of the heart grows weaker
- Pleural effusion (excess fluid around lungs)
- Swelling in abdomen (ascites)
- Swelling in ankles and legs
Other Symptoms May Include

- Decreased alertness or concentration
- Decreased urine output
- Need to urinate at night
- Infants may sweat during feeding (or other activity)
New York Heart Association (NYHA) Functional Classifications

NYHA Functional Classification provides a simple way of classifying the extent of heart failure.

<table>
<thead>
<tr>
<th>NYHA Class</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>No symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc.</td>
</tr>
<tr>
<td>II</td>
<td>Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.</td>
</tr>
<tr>
<td>III</td>
<td>Marked limitation in activity due to symptoms, even during less-than-ordinary activity e.g. walking short distances. Comfortable only at rest</td>
</tr>
<tr>
<td>IV</td>
<td>Severe limitations. Experiences symptoms even while at rest. Mostly bed bound patients.</td>
</tr>
</tbody>
</table>
Clinical Assessment

- Fluid in the lungs on auscultation
- Pitting edema of the legs
- Pelvic congestion
- Distended liver
- Distended jugular veins
- Irregular heart rhythm
Jugular Venous Distention
Diagnostic Tests to confirm diagnosis

- Chest X-ray
- ECG
- Echocardiogram
- Cardiac stress tests
- Heart catheterization
- Nuclear heart scans
Inotrope Mechanism of Action

• Stimulates an injured or weakened heart to pump harder to send blood through the body

• Increases cardiac output

• Decreases preload and afterload
Mechanism of Action Continued

Increases force of contraction

\[ \downarrow \]

Increases ejection of blood

\[ \downarrow \]

Decreases wall tension

\[ \downarrow \]

Improves oxygenation
Role of the Inotrope

- IV inotropes play a valuable role in improving the quality of life and functionality of end stage CHF patients who don’t qualify for transplant or LVAD

- These patients will usually remain on service long term
Role of the Inotrope

• Positive inotropic therapy is administered to relieve symptoms due to poor perfusion and to preserve end-organ function in patients with severe cardiac dysfunction or dilated cardiomyopathy

• It is of greatest value in patients with hypotension who have had no response to vasodilators and diuretics
Agents Commonly Used in Alternate Site

• Milrinone
• Dobutamine
• Dopamine
Contraindications

- Hypersensitivity to any component of the medication

- Patients with severe outflow obstruction, such as aortic stenosis or pulmonary stenosis
Side Effects

• Chest pain
• Headache
• Hypertension
• Increased ventricular ectopy
• Nausea
• Palpitations
• Shortness of breath
• Tachycardia
Patient Selection Criteria—
The Patient Should:

• Be reliable, teachable and compliant

• Live within a reasonable distance from the office/nursing staff with a functional telephone

• Have a functional central line

• Have a significant other living with them who is also trained in all aspects of the therapy
Patient Selection Criteria

• Have chronic intractable CHF

• Frequent hospitalization in spite of maximum oral medication therapy

• Be a New York Heart Association functional Class III or IV (may be awaiting transplant)

• On maximum doses of Digoxin, an ACE inhibitor, or a vasodilator, carvedilol, and a loop diuretic
Patient Selection Criteria

• Arrhythmias should be controlled prior to discharge

• Inotropic therapies may speed up the heart rhythm and cause arrhythmias

• Many adult patients may have Automatic Implanted Cardioverter/Defibrillator (AICD)

• Pediatrics patients will not usually have an AICD
Equipment Required in the Home If not on Telehealth

• A reliable bathroom scale
• An automatic blood pressure cuff that also measures heart rate
• A tape measure
• A thermometer
• Back up infusion pump
Telehealth in CHF Management

• Patients are monitored via electronic transmission of their medication intake, exercise, vital signs, weight etc.

• They can participate in video conferencing with nurses or physician specialists

• Widely used by the Veteran’s Administration

• Study by Intel and Aetna presented at AHIP Institute showed evidence of reduced rehospitalization and health care costs
Nursing Assessment and Interventions

Patients should receive a full body assessment with every visit including:

• Heart sounds
• Lung sounds
• Fluid retention (including neck veins)
• Record of weight and vital signs
• Record of intake and output
• Medication profile
• Changes in diet
Nursing Interventions

• Patient education is crucial
  – Medication
  – Side effects
  – Monitoring of vital signs
  – Nutrition

• Pre-discharge interview with the patient is recommended
Nursing Interventions
Patient Teaching

Patients will be instructed in the following topics:

• Measure daily weight, BP, HR and abdominal girth (if required)
• Self infusion of medication and maintenance of IV catheter
• Nutritional instruction including:
  – Fluid and sodium restrictions
  – How to understand nutrition labeling
Nursing Intervention

Teaching regarding sodium is a MUCH bigger issue than just avoiding table salt.
Nursing Interventions

A two to three pound weight gain needs to be investigated!
Nursing Interventions

• Communication of your findings with the multidisciplinary team
  – MD
  – Pharmacy
  – Nursing team
Goal is to Prevent Re-hospitalization

• One of the most common factors that precipitates rehospitalization for heart failure is non-compliance by the patient to their medical regimen, or their sodium or fluid restrictions.

• Key is to educate the patient and monitor their status frequently.
Administration – Vascular Access Device

- Centrally placed vascular access device (VAD) with the tip terminating in the superior vena cava
  
- PICC
- Port
- Hickman
- Groshong

- Note: Peripheral IV catheters are **not** appropriate for home use
Administration Methods

• Infusion of inotropic medications requires an ambulatory infusion device with alarm
Continuous Infusion

- In the case of continuous infusion, there is documentation of deterioration in clinical status when the drug is tapered or discontinued under observation in the hospital.

- Nurse provides cassette changes until patient is comfortable and proven competent.

- Remember this is a high risk patient.
Intermittent Infusion

- There is documentation of repeated hospitalizations for CHF despite maximum medical management

- The patient is maintained on the lowest practical dose and efforts to decrease the dose of the drug or the frequency/duration of infusion are documented during the first 3 months of therapy

- ACC/AHA guidelines do not support intermittent use in the home care setting.
Pharmacy Considerations and Mixing

- Medication stability is limited secondary to <797> guidelines

- Every other day bag change

- Back up bag should be present in the home

- Instruct patient to rotate the stock so that the oldest is used and label should reflect these instructions

- Check with MD regarding weight changes as inotropic dose may not be appropriate to change

- An adjustment may be done in oral medications
Pharmacy Monitoring

These patients are high priority patients and are classified as high risk in emergency planning.

Weekly updates must include:
• Overall patient condition
• Vascular Access Device Status
• Weight
• Urine Output
• Shortness of Breath
• Activity Level
• Fluid and Electrolyte status
Pharmacy Services Provided

Pharmacy will:

• Ensure that patients have the appropriate dosage of drug and a back-up bag in their home

• Malfunctioning pumps will be replaced immediately

• Patient’s status will be monitored between nursing visits by phone so that deterioration can be caught quickly
Left Ventricular Assist Device

- A LVAD is a small pump implanted in a patient’s chest to support a failing heart. They have taken the place of inotropes to keep a patient alive while awaiting transplant, or in some cases in place of transplant. The 2 year survival rate is approx. 60%, about the same as a transplant.
Reimbursement Guidelines

For end-stage CHF patients who are not eligible for transplant, inotropic therapy may be a long-term proposition. It may be in the patient’s best interest to evaluate them for Medicare coverage criteria even if they have private insurance.

For private insurance companies, we should ask for a determination of coverage even if they say no pre auth is necessary.
Reimbursement Benefits

• Private Insurance – may not be as strict as Medicare coverage criteria

• Medicare – Part B will have a 20% co-payment
  Part D will have a co-payment and donut hole

• Medicaid - may have better coverage than other providers
Medicare Coverage Criteria

- Medicare has strict criteria that must be met in order for patient to have coverage
  - Dyspnea at rest is present despite treatment with maximum or near maximum tolerated doses of digoxin, loop diuretics, and an angiotension converting enzyme (ACE) inhibitor or another vasodilator
    - Examples: Digoxin, Furosemide, Carvedilol
    - Exception: Patient allergic
Medicare Coverage Criteria

Patients should have invasive hemodynamic studies performed within the past 6 months with the following results prior to the initiation of inotropic therapy:

• Cardiac Index less than or equal to 2.2
• Pulmonary Capillary Wedge Pressure greater than or equal to 20
Medicare Coverage Criteria

• A right heart catheterization done after starting the inotrope with evidence of a 20% increase in the Cardiac Index or a 20% decrease in the Pulmonary Capillary Wedge Pressure, with results documented on the Home Parenteral Inotropic Therapy Data Collection Form. There also needs to be a CMN prepared by the ordering physician.
Inotrope Dose Range Requirements

• Dobutamine 2.5 -10 mcg/kg/min

• Milrinone 0.375 – mcg/kg/min

• Dopamine < than or = to 5 mcg/kg/min
Home Parenteral Inotropic Therapy Data Collection Form (NOT INCLUSIVE FORM)

Home Parenteral Inotropic Therapy: Data Collection Form
- Patient’s Name: ___________________________ HIC#: __________________
- Neither the supplier nor anyone in a financial relationship with the supplier may complete the information below.
- 1) Results of invasive hemodynamic monitoring or impedance cardiography:
  - Cardiac Index
  - Wedge Pressure
  - Date
    - Before inotrope infusion: ____________
    - On inotrope infusion: ____________
  - Drug: __________________ Dose: ____________ mcg/kg/min
- 2) Cardiac drugs (digoxin, diuretics, vasodilators) immediately prior to inotrope infusion (list name, does, frequency):
- 3) Does this represent maximum tolerated does of these drugs?
- 4) Breathing status (check in each column):
- 5) Initial home prescription: Drug: __________________ Dose: ____________ mcg/kg/min
  ______ hrs/day _________ days/week (or every _______ days).
- 6) If continuous infusion is prescribed, have attempts to discontinue inotrope infusion in the hospital failed?
- 7) If intermittent infusion is prescribed, have there been repeated hospitalizations for heart failure during which parenteral inotropes were required?
- 8) Is the patient capable of going to the physician for outpatient evaluations?
- 9) Is the routine electrocardiographic monitoring required in the home?
- The above statements and any additional explanations included separately are true and accurate and there is documentation present in the patient’s medical record to support these statements.
- Physician Signature: ___________________________________________ Date: ____________
- Physician Name Printed/Typed: ___________________________________________ UPIN# ________
- Physician Specialty: ___________________________________________
# Reimbursement Considerations - Inotropic

<table>
<thead>
<tr>
<th>Benefits/coverage</th>
<th>Medicare</th>
<th>Aetna</th>
<th>BlueCross/BlueShield</th>
<th>UHC</th>
<th>Gentiva CareCentrix</th>
</tr>
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<td>Coverage for Dobutamine, Milrinone and Dopamine for patients with congestive heart failure and depressed cardiac function.</td>
<td>Patient must have a qualifying diagnosis as determined by Case Management.</td>
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| Authorization Requirements | Patient must have dyspnea at rest or with minimal exertion. Drug doses must be within specific ranges per Medicare guidelines and cardiac studies must be performed within 6 months of SOC. | All Inotropic patients require auth prior to SOC. | All Inotropic patients require auth prior to SOC. | All Inotropic patients require auth prior to SOC. |

| Documentation Requirements | Inotropic Data Collection Form must be completed by the physician and approval from Management and/or Medicare Supervisor before therapy is initiated. Must have a completed DIF and signed detailed physician orders on file before submitting claim. | MD orders and History/Physical or other pertinent clinical information available | MD orders and History/Physical or other pertinent clinical information available | MD orders and History/Physical or other pertinent clinical information available |

| Additional Coverage Rules | The patient is maintained on the lowest practical dose and efforts to decrease dose are documented during the first 3 months of therapy and the patient's cardiac symptoms, vital signs, weight, lab values and response to therapy are documented in patient's medical record. Properly executed ABN on file if patient does not meet criteria. | | | |


Think Hospital to Home
Conclusion

- Therapy is safe and effective for the home care population
- Patient selection
- Ensure adequate insurance coverage
- Ensure patient met established criteria if required by the insurance carrier
- Importance of Nursing competency
- Appropriate nursing interventions
- Collaboration of care
- Communication
Questions
References

• cms.gov/medicare-coverage-database – Home Parenteral Inotropic Data Collection Form
• AHA/ACC Guidelines for the Evaluation and Management of Chronic Heart Failure in the Adult: Executive Summary Update 2005
• Eweek.com/c/a/health-care/Intel-Telehealth System Helps Heart Failure Patients June 2010
Learning Assessment Questions & Answers

Please refer to the NHIA Annual Conference & Exposition 2012 On-Site Program for a brief post-test.

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