Special Considerations in COPD Management

CLINICAL PEARL SESSION

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Objectives

- **Pharmacist objectives:**
  - Evaluate the recent literature comparing combination therapy (dual bronchodilator vs bronchodilator with inhaled glucocorticoid) in patients with COPD who have a high risk for exacerbations.
  - Describe specific patient characteristics that may impact a patient’s ability to use different inhaler devices appropriately and/or may impact effectiveness of the inhaled therapy.

- **Pharmacy Technician objectives:**
  - List available treatment options for COPD management in patients at high risk for exacerbation.
  - Identify patient characteristics that may lead to inappropriate inhaler use.

Abbreviations

- FEV1: Forced Expiratory Volume in one second
- FVC: Forced Vital Capacity
- CAT™: COPD Assessment Test
- mMRC: Modified British Medical Research Council questionnaire
- LAMA: Long Acting Antimuscarinic Agent
- LABA: Long Acting Beta-2 Agonists
- ICS: Inhaled Corticosteroid
Impact of COPD

- 3rd leading cause of death in the US
- 12 million diagnosed in US
  - Millions undiagnosed
- Morbidity and mortality
  - Women > Men
- Costs the US ~$50 billion per year

NEW inhaled therapies available

<table>
<thead>
<tr>
<th>Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Combination Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-Acting Beta-2 Agonists (LABAs)</td>
<td>Aformoterol (R-enantiomer of formoterol)</td>
<td>Brovana® Inhalation solution</td>
<td>Glycopyrrolate/indacaterol (Utiom Noshaler®)</td>
</tr>
<tr>
<td></td>
<td>Indacaterol</td>
<td>AstraZeneca®</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Olodaterol</td>
<td>Breezhaler®</td>
<td>DosageForm Therapeutic Inhaler (Symbicort®)</td>
</tr>
<tr>
<td></td>
<td>Vilanterol</td>
<td>N/A</td>
<td>Palminthol/Vilanterol (Breo Ellipta®)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Gilenya/Vilanterol (Apa Ellipta®)</td>
</tr>
<tr>
<td></td>
<td>Achloroamin</td>
<td>Tudorza®</td>
<td></td>
</tr>
<tr>
<td>Long-Acting Antimuscarinics (LAMAs)</td>
<td>Aclidinium</td>
<td>Tudorza®</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Glycopyrrolate</td>
<td>Seebri®</td>
<td>Glycopyrrolate/indacaterol (Utiom Noshaler®)</td>
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<td>Glycopyrrolate</td>
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<td></td>
<td>Glycopyrrolate</td>
<td>Utibron Neohaler®</td>
<td>Glycopyrrolate/formoterol (Bevespi Aerosphere®)</td>
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<td>Glycopyrrolate</td>
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</table>

Update: GOLD 2017 Guideline

- Major revision from 2016 report
- Disease assessment
- Management of stable COPD
  - New inhaled therapies
  - Use of combination inhaled therapies
    - In those at high risk for exacerbations
    - Dual bronchodilator vs bronchodilator + inhaled corticosteroid
- Adherence to inhaler therapy
Diagnosis and Assessment

- **Diagnosis:**
  - Spirometry
    - FEV1/FVC < 0.7 → airflow limitation
- **Assessment (changed from 2016 guidelines):**
  - FEV1 → severity of airflow limitation
  - Symptom assessment
    - CAT™ (recommended)
    - mMRC
  - Exacerbation risk

Combined assessment to determine Group to guide inhaler therapy

Determination of GOLD Groups

<table>
<thead>
<tr>
<th>≥2 exacerbations or ≥1 leading to hospitalization in past year</th>
<th>mMRC 0-1</th>
<th>CAT &lt; 10</th>
<th>Group C</th>
<th>Group D</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 1 exacerbations in the past year (not leading to hospitalization)</td>
<td>mMRC ≥ 2</td>
<td>CAT ≥ 10</td>
<td>Group A</td>
<td>Group B</td>
</tr>
</tbody>
</table>

GOLD 2017 Treatment Guidelines
Management of Stable COPD

<table>
<thead>
<tr>
<th>Group C</th>
<th>Group D</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAMA → LAMA + LABA</td>
<td>LAMA + LABA → LAMA + LABA + ICS</td>
</tr>
<tr>
<td>LAMA + LABA + ICS</td>
<td></td>
</tr>
<tr>
<td>* If single bronchodilator chosen initially, LAMA preferred</td>
<td></td>
</tr>
<tr>
<td>Group A</td>
<td>Group B</td>
</tr>
<tr>
<td>Bronchodilator → alternative bronchodilator</td>
<td>LABA or LAMA → LAMA + LABA</td>
</tr>
</tbody>
</table>
Management for those at high risk for exacerbation: Group C

- Group C
  - LAMA superior to LABA for exacerbation prevention (Level of Evidence A)
    - Trials:
      - POST-COPD 2011 (salmeterol vs tiotropium)
      - INTEGRATE 2013 (indacaterol vs tiotropium)
  - For persistent exacerbations, LAMA + LABA combination preferred over LABA + ICS
    - Increased risk for pneumonia with ICS for some (Level of Evidence A)

GOLD: 2017 report.

Management for those at high risk for exacerbation: Group D

- Group D
  - LAMA + LABA superior to monotherapy or LABA/ICS for exacerbation prevention (Level of Evidence B)
    - Trials:
      - SPARK 2013 (indacaterol + glycopyrronium vs glycopyrronium vs tiotropium)
      - FLAME 2016 (indacaterol + glycoyrronium vs salmeterol + fluticasone)
  - Higher risk for developing pneumonia on ICS (Level of Evidence A)
  - Consider LABA/ICS as initial for special circumstances
    - Asthma-COPD overlap
    - High eosinophil count (controversial)

GOLD: 2017 report.

Question to the Audience

- Are you confident in your ability to adequately educate a patient to use an inhaled therapy?
Issues with inhaled therapy administration

- Poor inhalation technique → poor disease control
- ~33 to 50% of patients use their inhalers correctly
  - Incorrect inhaler technique reported as high as 94%!
  - Incorrect inhalation technique associated with:
    - Inhaler type (conflicting evidence)
    - Not provided inhalation instructions/education
    - Patient factors
      - Age, sex, educational level, emotional problems, severity of disease, comorbidities

Administration Errors

- All inhalers:
  - Not removing mouthpiece cap
  - Incorrect sequence of multiple inhalers
- Metered dose inhalers:
  - Lack of coordination breath and actuation
  - Not holding breath adequately
  - Rapidly inhaling
  - Not shaking or priming inhaler
- Dry powder inhalers:
  - Holding device upside down
  - Exhaling into the device
  - Inhaling too weakly/slowly
  - Storing in humid environment

BEWARE OF LOOK-A-LIKES!

- Be sure patients understand the differences between inhalers and when to use each
<table>
<thead>
<tr>
<th>Inhaler type</th>
<th>Advantages</th>
<th>Limitations/Common Errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metered dose inhalers</td>
<td>Compact, portable, Consistent dosing, Rapid delivery</td>
<td>Use affected by inadequate hand-breath coordination, poor fine motor control, hand/finger muscle weakness</td>
</tr>
<tr>
<td>Dry powder inhalers</td>
<td>Compact, portable, Do not require hand-breath coordination, Do not require hand strength</td>
<td>Require adequate inspiratory flow rate, may require more steps to prepare (capsule)</td>
</tr>
<tr>
<td>Soft mist inhalers</td>
<td>Compact, portable, High lung deposition, Rapid delivery</td>
<td>Requires hand-breath coordination (may be easier than MDIs)</td>
</tr>
<tr>
<td>Nebulizers</td>
<td>Only require normal tidal inspiration, Combination not required</td>
<td>Longer time for drug administration, cleaning required, not as portable</td>
</tr>
</tbody>
</table>

How do you choose device type?

- Cost/insurance coverage
- Combination products to minimize device types needed
- Match device with patient ability
  - Assess patient’s ability through patient demonstration of technique
  - Consider ability to coordinate actuation with inhalation
  - Consider inspiratory flow
- Patient preference

Education

- Healthcare providers
  - Must be educated on correct use of inhalers
  - Obtain placebo devices to educate patients
- Patients
  - Thorough training prior to prescribing
  - Assess inhaler technique at each visit (especially if going to be changing therapy)
  - Train, assess, and monitor
  - Use visual cues (such as stickers on inhalers) to help improve home inhaler use especially if using multiple devices
Conclusions

- LAMA/LABA (long-acting beta agonist and long-acting antimuscarinic) combination now preferred over addition of ICS (inhaled corticosteroid) for those at high risk of exacerbation
- Large percentage of patients do not use inhaled therapy correctly, which impacts clinical outcomes
- Choosing appropriate inhaled therapy that the patient is able to administer correctly is important for control of COPD
- Assessing inhaler technique at each visit and providing education is essential

References


Assessment Question 1

- NB is a 64yo female with COPD (GOLD Group D), HTN, diabetes, and hypothyroidism. She has had 2 COPD exacerbations in the past year, 1 of which required hospitalization. She is frustrated with her current medication routine due to its complexity. She is currently using salmeterol 50mcg BID and albuterol 90mcg q6h PRN. Which of the following is the most appropriate adjustment to her inhaled therapy regimen (assuming her insurance covers all options)?
  A. Add tiotropium to current regimen
  B. Change salmeterol to salmeterol/fluticasone combination
  C. Stop albuterol and start ipratropium
  D. Stop salmeterol and start olodaterol/tiotropium combination
Assessment Question 2

RL is a 78yo man with COPD (GOLD Group B) and severe Alzheimer’s disease who requires the assistance of his daughter to administer his metered dose inhaler. Which inhaled device is most preferred for this patient to ensure the patient is receiving adequate bronchodilator therapy?
A. Diskus dry powder inhaler
B. Nebulizer
C. Soft mist inhaler
D. Handihaler dry powder inhaler