

Pharmacologic Options for Chronic Obstructive Pulmonary Disease (COPD)

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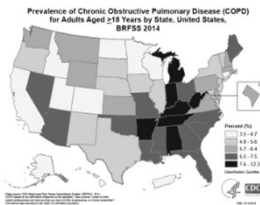
Global Initiative for Chronic Obstructive Lung Disease: Global Strategy for Diagnosis, Management, and Prevention of COPD

- COPD is a common, preventable, and treatable disease characterized by
 - Persistent respiratory symptoms
 - Airflow limitation
- Disease and resulting symptoms are due to airway and/or alveolar abnormalities
 - Usually caused by significant exposure to noxious particles or gases

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COPD Prevalence

- COPD is currently the 4th leading cause of death globally
- Projected to be 3rd leading cause by 2020



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Centers for Disease Control

Symptoms of COPD

- Common symptoms
 - Dyspnea
 - Shortness of breath
 - Sense of increased effort to breathe, chest heaviness
 - Chronic and progressive dyspnea is the most characteristic symptom of COPD
 - Chronic cough
 - Often the first symptom of COPD
 - Chronic sputum production

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Pathophysiology of COPD

- COPD is caused by a combination of small airway disease (ex. obstructive bronchiolitis) and parenchymal destruction (emphysema)
- Chronic inflammation → structural changes
 - Small airways become narrower & lung parenchyma is destroyed
 - Decreased lung elastic recoil
- Several factors lead to progressive airflow limitation in COPD patients

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Chronic Obstructive Lung Disease (COPD)

- COPD risk factors
 - Cigarette smoking is the main risk factor
 - Environmental exposures
 - Occupational
 - Air pollution
 - Genetics
 - Alpha-1 antitrypsin deficiency (AATD)
 - Abnormal lung development
 - Infections
 - Socioeconomic status

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Diagnosis of COPD

- COPD diagnosis should be considered in any patient with the hallmark symptoms (dyspnea, chronic cough, chronic sputum production), along with exposure to risk factors

- Spirometry is required to make the diagnosis
 - $FEV_1/FVC < 0.70$

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COPD Assessment

- Goals of COPD assessment
 - Determine degree of airflow limitation
 - Spirometry
 - Determine impact of disease on patient's overall health status
 - Symptoms
 - Quality of life
 - Comorbidities
 - Determine risk of future events
 - Exacerbations
- Gaining an overall picture of the patient's disease state and health status will help guide therapy

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COPD Assessment

1. Classify airflow obstruction severity

- Spirometry is used to diagnose and classify the patient's airflow status

GOLD 1	Mild	$FEV_1 \geq 80\%$ predicted
GOLD 2	Moderate	$50\% \leq FEV_1 < 80\%$ predicted
GOLD 3	Severe	$30\% \leq FEV_1 < 50\%$ predicted
GOLD 4	Very Severe	$FEV_1 < 30\%$ predicted

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COPD Assessment

2. Assess symptoms

- mMRC Questionnaire
 - Measures dyspnea/ breathlessness
- COPD Assessment Test (CAT)
 - Comprehensive assessment of symptoms
- COPD Control Questionnaire (CCQ)
 - Comprehensive assessment of symptoms

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COPD Assessment

3. Combine patient's spirometric classification with the symptomatic assessment and exacerbation risk

Exacerbation history	≥2 or ≥1 leading to hospitalization	C	D
	0 or 1 (not leading to hospitalization)	A	B
		mMRC 0-1 CAT <10	mMRC ≥2 CAT ≥10
		Symptoms	

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COPD Assessment

- GOLD classification into Groups A-D provides recommendations for initial therapy, as well as treatment escalation and/or de-escalation strategies
- Example
 - Patient with mMRC of 2, CAT of 12, and no exacerbations, FEV₁ of 60% predicted
 - GOLD Grade 2
 - Moderate airflow obstruction
 - GOLD Group B

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COPD Prevention and Maintenance Therapy

- Non-pharmacologic therapy
 - Smoking cessation is key
 - Greatest capacity to influence the natural course of COPD
 - Pharmacotherapy + behavioral support increases smoking cessation rates
 - Vaccinations
 - Influenza vaccination
 - Can reduce serious illness and death in COPD patients
 - Pneumococcal vaccine
 - PCV13 & PPSV23
 - Recommended for all patients 65 and older, and for younger patients in certain cases (ex. those with significant comorbidities)

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COPD Prevention and Maintenance Therapy

- Non-pharmacologic therapy
 - Pulmonary rehabilitation
 - “Comprehensive intervention based on thorough assessment followed by patient-tailored therapies”
 - Exercise training, education, nutrition, etc.
 - Improves symptoms, quality of life, and participation in daily activities
 - Oxygen therapy
 - Increases survival in patients with severe resting hypoxemia
 - Should not be used routinely in patients with stable COPD
 - Surgical intervention
 - May be beneficial in select patients with advanced emphysema
 - Palliative care
 - Symptom control in advanced COPD to prevent and relieve suffering

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COPD Maintenance Therapy

- Pharmacologic therapy
 - Reduce symptoms
 - Reduce severity and frequency of exacerbations
 - Improve health status and exercise tolerance
- Currently, no existing COPD medications are available that can modify the long-term decline in lung function
 - Treatment is focused on reducing symptoms and exacerbations

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COPD Pharmacologic Therapy

- Medication therapy should be individualized based on
 - Symptom severity
 - Exacerbation risk
 - Side effects
 - Comorbidities
 - Medication availability and cost
 - Patient's clinical response and ability to utilize various delivery devices

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COPD Pharmacologic Therapy

- Bronchodilators
 - β_2 -agonists
 - Anticholinergic agents
 - Methylxanthines
 - Combination therapy
- Anti-inflammatory agents
 - Inhaled corticosteroids
 - PDE4 inhibitors

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Pharmacologic Therapy for COPD: Bronchodilators

- Bronchodilators
 - Alter airway smooth muscle tone
 - Improve spirometric variables (ex. FEV₁) by widening the airways
 - Reduce hyperinflation and improve exercise tolerance
 - Central to symptom management
 - Commonly given on a regular basis to prevent and/or reduce symptoms

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Pharmacologic Therapy for COPD: Bronchodilators

- β_2 -agonists
 - Relax smooth muscles in the airways by stimulating β_2 receptors
- Adverse effects
 - Resting sinus tachycardia
 - Can precipitate cardiac arrhythmias
 - Tremor
 - Upper respiratory infection
 - Pharyngitis
 - Anxiety
 - Toxicity is dose-related

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Pharmacologic Therapy for COPD: Bronchodilators

- β_2 -agonists
 - Short-acting β_2 -agonists (SABAs)
 - Albuterol (ProAir Respiclick, Ventolin HFA, Proventil HFA, etc.)
 - Levalbuterol (Xopenex)
 - Long-acting β_2 -agonists (LABAs)
 - Formoterol (Perforomist) } Twice daily
 - Salmeterol (Serevent Diskus) } Twice daily
 - Indacaterol (Arcapta Neohaler) } Once daily
 - Oladaterol (Striverdi Respimat) } Once daily
 - Arformoterol (Brovana)

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Pharmacologic Therapy for COPD: Bronchodilators

- Anticholinergic (anti-muscarinic) agents
 - Block the bronchoconstriction effects of acetylcholine on M3 muscarinic receptors on bronchial smooth muscle
 - Long-acting muscarinic agents (LAMAs) have a greater effect on reducing exacerbations than long-acting β_2 -agonists (LABAs)
- Adverse effects
 - Anti-muscarinic agents are poorly absorbed which limits the negative systemic effects
 - Extensive use and research has shown these products to be very safe
 - Dry mouth is the main side effect
 - Some patients report a bitter, metallic taste
 - Pharyngitis & sinusitis

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Pharmacologic Therapy for COPD: Bronchodilators

- Anti-muscarinic agents
 - Short-acting muscarinic agents (SAMAs)
 - Ipratropium (Atrovent)
 - Long-acting muscarinic agents (LAMAs)
 - Tiotropium (Spiriva) } Once daily
 - Umeclidinium (Incruse Ellipta) }
 - Aclidinium (Tudorza Pressair) }
 - Glycopyrronium bromide (Seebri Neohaler) } Twice daily

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Pharmacologic Therapy for COPD: Bronchodilators

- Methylxanthines
 - Theophylline
 - Modest bronchodilator effect in stable COPD
 - Several adverse effects
 - Palpitations/arrhythmias
 - Convulsions
 - Headache
 - Insomnia
 - Nausea
 - Heartburn
 - Small therapeutic ratio
 - Most of the benefit occurs only when doses are near the toxic level
 - Clearance of this medication decreases with age
 - Significant interactions with other commonly used medications

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Pharmacologic Therapy for COPD: Bronchodilators

- Combination bronchodilator therapy
 - Utilizing more than 1 medication with differing mechanisms of action and durations can increase the degree of bronchodilation and reduce symptoms, while minimizing adverse effects (compared with increasing the dose of a single agent)
- There are multiple combinations of LABA and LAMA available in a single inhaler
 - Tiotropium/olodaterol (Stiolto Respimat)
 - Umeclidinium/vilanterol (Anoro Ellipta)
 - Glycopyrrolate/formoterol (Bevespi Aerosphere)
 - Glycopyrrolate/indacaterol (Utibron Neohaler)

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Pharmacologic Options for COPD

- Anti-inflammatory agents
 - Inhaled corticosteroids
 - Used in combination with a long-acting bronchodilator
 - More effective than individual components in improving health status and lung function, as well as reducing exacerbations in those with moderate to very severe COPD
 - PDE-4 inhibitors
 - Useful in patients with chronic bronchitis, and severe to very severe COPD with a history of exacerbations
 - Reduces exacerbations and improves lung function
 - *Anti-inflammatory agents are primarily utilized for their exacerbation benefit*

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Pharmacologic Options for COPD: Anti-inflammatory Agents

- Inhaled corticosteroids (ICS)
 - Used in combination with a long-acting bronchodilator
 - Improve lung function and health status, as well as reduce exacerbations in those with moderate to very severe COPD
 - Adverse effects
 - Increased prevalence of
 - Oral candidiasis (thrush)
 - Hoarse voice
 - Skin bruising
 - Pneumonia

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Pharmacologic Options for COPD: Anti-inflammatory Agents

- ICS products
 - Fluticasone (Flovent)
 - Budesonide (Pulmicort)
- Combination of ICS + long-acting bronchodilator
 - Budesonide/formoterol (Symbicort)
 - Fluticasone/salmeterol (Advair)
 - Fluticasone/vilanterol (Breo Ellipta)

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**Pharmacologic Options for COPD:
Anti-inflammatory Agents**

- PDE-4 inhibitors
 - Roflumilast (Daliresp)
 - Once daily oral medication
 - Reduces inflammation, but no direct bronchodilator activity
 - Reduces moderate and severe exacerbations
 - Adverse effects: nausea, diarrhea, reduced appetite, weight loss, abdominal pain, sleep disturbance, headache, etc.
 - Occur early during treatment, but are reversible and diminish over time with continued treatment

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Pharmacologic Options for COPD

- Triple inhaled therapy
 - LABA + LAMA + ICS
 - Improve lung function, symptoms, and health status
 - Reduced exacerbation risk when adding LAMA to LABA/ICS
 - Trelegy Ellipta (fluticasone, umeclidinium, and vilanterol)
 - FDA approval September 2017
 - 1st once daily product approved in the US that combines all 3 classes in a single inhaler

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Pharmacologic Options for COPD

- Other treatment options
 - Oral glucocorticoids
 - Utilized in treatment of acute exacerbations, but have no role in the chronic daily treatment of stable COPD
 - Lack of benefit vs. high rate of systemic side effects
 - Antibiotics
 - Long-term azithromycin and erythromycin therapy reduces exacerbations over 1 year
 - Treatment with azithromycin is associated with increased bacterial resistance and hearing impairments
 - Mucolytics/antioxidants
 - Routine use of acetylcysteine may reduce the risk of exacerbations in select patients (ex. those not receiving ICS)

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Pharmacologic Options for COPD

- Other pharmacologic treatments
 - Alpha-1 antitrypsin augmentation therapy
 - IV therapy may slow the progression of emphysema in those with AATD (specific genetic marker)
 - Antitussives
 - No conclusive evidence of benefit in COPD
 - Vasodilators
 - Used in pulmonary hypertension, but do not improve COPD outcomes, may actually worsen oxygenation levels

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Pharmacologic Options for COPD: Issues Related to Inhaled Delivery

- Inhalation devices
 - Metered-dose inhalers (MDI)
 - Require good hand-breath coordination, priming & shaking prior to use
 - Dry powder inhalers
 - Less coordination required
 - Patient must be able to produce adequate inhalation (quick, deep breath)
 - Soft-mist inhalers
 - Nebulizers
 - More expensive and time-intensive

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Pharmacologic Options for COPD: Issues Related to Inhaled Delivery

- More than 2/3 of patients make at least one mistake in using their inhalation device
- Significant relationship between incorrect inhaler use and poor symptom control in COPD patients
- Poor inhaler technique can be caused by
 - Elderly patients
 - Use of multiple devices
 - Lack of proper education

Pharmacologic Options for COPD: Issues Related to Inhaled Delivery

- Key mistakes in delivery device use due to problems with
 - Inhalation rate
 - Inhalation duration
 - Coordination
 - Dose preparation
 - Exhalation prior to inhalation
 - Holding breath after inhalation

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Pharmacologic Options for COPD: Issues Related to Inhaled Delivery

- Inhaler technique
 - The choice of inhaler should be individualized to each patient based on
 - Cost
 - Access
 - Patient's ability and preference
 - Essential to provide instructions and demonstration of the proper technique with each device
 - Teach-back method
 - **Inhaler technique should be assessed before concluding that the current therapy is ineffective**

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Pharmacologic Options for COPD

TABLE 3. FDA-APPROVED COPD DRUGS ^{1,2,3,4}				
	Brand/Device (Chemical name)	Classed Uses	Strengths	Limitations
Dry Powder Inhaler (DPI)	AccuNeb Diskus (Glycopyrronium bromide)	Prescribed with three inhalations, twice daily dosing	Two breaths and expiratory coordination required	Patients must inhale deeply with good force. Preparation steps could challenge patients with arthritis, low dexterity, or poor grip strength.
	Spiriva Handihaler (tiotropium bromide)	Need to cover expiration valve each use, once-daily dosing		
	Prohaler Respimat (salmeterol)	Need to cover expiration valve each use, once-daily dosing		
	Foracort Pressor (formoterol bromide)	8/12 dosing		
Metered-Dose Inhaler (MDI)	Asmanex Ellipta (fluticasone furoate)	Once-daily dosing	Preloaded inhaler with dose counter	Must be read administration via the counter
	Flex E245 (fluticasone furoate)/ vilanteril	Once-daily dosing	Single-step, low preparation, ready to use for patients with poor grip strength or dexterity.	
	Asmanex Ellipta (fluticasone furoate)/ vilanteril	Once-daily dosing	Has a unique resistance system in the mouthpiece that allows for easier inhalation, easy to read dose counter	
Soft Mist Inhaler	Spiriva Respimat (tiotropium)	Once-daily dosing	Slow-moving mist, patients can breathe slower and more normally, exhalation step unnecessary	Must be sure patients inhale to read dose counter
	Striverdi Respimat (vandevanteril)	4 inhalations once daily		
	Prohaler Respimat (salmeterol)	4 inhalations once daily		
	Combination Respimat (opiropium bromide)/ vilanteril	Only one device for COPD medication that uses Respimat technology (combination QD2)		

Wick, J. COPD: Delving into Inhaler Adherence, Pharmacy Times, November 22, 2017.

Management of Stable COPD

- Choice of pharmacologic therapy should be individualized based on assessing the patient's symptoms and risk of exacerbations
- Non-pharmacologic measures should be emphasized
 - Identify and reduce exposure to risk factors
 - Smoking cessation
- Main treatment goals
 - Reduce symptoms
 - Reduce exacerbation risk and severity
 - No currently available medications can reverse lung function decline
 - No options for "cure" at this time

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Treatment of Stable COPD

- Initiation of medication should be based on the patient's symptoms and exacerbation risk, as outlined in by the GOLD group classification
 - This treatment algorithm also allows for escalation (or de-escalation) based on changes in symptomology and exacerbation risk
- Continuous monitoring and evaluation of
 - Risk factor exposure
 - Disease progression
 - Adverse effects of medications
 - Effectiveness of medications
 - Exacerbation history
 - Comorbidities

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Treatment of Stable COPD

Exacerbation History	≥2 or ≥1 leading to hospitalization	C	D
	0 or 1 (not leading to hospitalization)	A	B
		mMRC 0-1 CAT <10	mMRC ≥2 CAT ≥10
		Symptoms	

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Treatment of Stable COPD

- Group A
 - Few exacerbations
 - 0 or 1 (not requiring hospitalization)
 - Fewer symptoms
 - CAT <10
 - mMRC 0-1
 - Short or long-acting bronchodilator

```
graph TD; A[Bronchodilator] -- Evaluate effectiveness --> B[Continue, stop, or switch to an alternate bronchodilator];
```

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Treatment of Stable COPD

Exacerbation History	≥2 or ≥1 leading to hospitalization	C	D
	0 or 1 (not leading to hospitalization)	A	B
		mMRC 0-1 CAT <10	mMRC ≥2 CAT ≥10

Symptoms

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Treatment of Stable COPD

- Group B
 - Exacerbations
 - 0 or 1 (not requiring hospitalization)
 - Symptoms have progressed
 - mMRC 2 or greater
 - CAT ≥10
- Group B patients are likely to have comorbidities that may add to their symptoms and impact prognosis

```
graph TD; A[Long-acting bronchodilator] -- Persistent symptoms --> B[Combination LABA + LAMA];
```

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Treatment of Stable COPD

Exacerbation History	≥2 or ≥1 leading to hospitalization	C	D
	0 or 1 (not leading to hospitalization)	A	B
		mMRC 0-1 CAT <10	mMRC ≥2 CAT ≥10

Symptoms

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Treatment of Stable COPD

- Group C
 - More exacerbations
 - ≥2 or 1 requiring hospitalization
 - Fewer symptoms
 - mMRC 0-1
 - CAT <10

```
graph TD; LAMA -->|Further exacerbations| LABA_LAMA[Combination LABA + LAMA (preferred)]; LAMA --> LABA_IC[Combination LABA + ICS];
```

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Treatment of Stable COPD

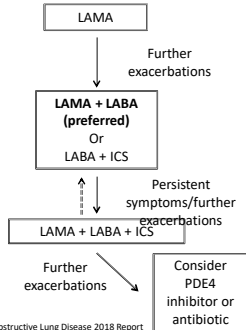
Exacerbation History	≥2 or ≥1 leading to hospitalization	C	D
	0 or 1 (not leading to hospitalization)	A	B
		mMRC 0-1 CAT <10	mMRC ≥2 CAT ≥10

Symptoms

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Treatment of Stable COPD

- Group D
 - Exacerbations
 - ≥2 or 1 requiring hospitalization
 - Symptoms have progressed
 - mMRC ≥2
 - CAT ≥10



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Non-Pharmacologic Treatment

- Smoking cessation
- Physical activity
- Flu vaccine
- Pneumococcal vaccination
- Pulmonary rehabilitation
 - GOLD Groups B-D

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Management of COPD Exacerbations

- A COPD exacerbation is defined as “an acute worsening of respiratory symptoms resulting in additional therapy”
- Complex event
 - Increased airway inflammation
 - Increased mucus production
 - Increased gas trapping
- These changes lead to increased dyspnea
 - Key symptom of a COPD exacerbation

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Management of COPD Exacerbations

- Symptoms
 - Increased dyspnea
 - Increased sputum volume/purulence
 - Increased cough and wheezing
- COPD exacerbations causes
 - Respiratory infections
 - Viral (most common)
 - Bacterial
 - Environmental triggers

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Management of COPD Exacerbations

- Exacerbation classification
 - Mild
 - Treated with short-acting bronchodilators only
 - Moderate
 - Treated with short-acting bronchodilators and/or oral corticosteroids
 - Severe
 - Patient requires hospitalization or visits ER & be associated with acute respiratory failure
- Inpatient vs. outpatient treatment depends on the severity
 - Hospitalization for an exacerbation is associated with poor prognosis and increased risk of death

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Management of COPD Exacerbations

- Goals of treatment
 - Minimize negative impact of current exacerbation
 - Prevent future exacerbations
- Exacerbations negatively impact
 - Hospitalization rates
 - Health status
 - Disease progression

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Management of COPD Exacerbations

- Initial bronchodilator used in treatment of COPD exacerbation
 - Short acting β_2 -agonist +/- short acting anticholinergic
- Systemic corticosteroids
 - Prednisone 40mg daily x 5 days
 - Shorten recovery time and improve lung function
- Antibiotics
 - Aminopenicillin with clavulanic acid, macrolide, or tetracycline
 - 5-7 days

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Management of COPD Exacerbations

- Maintenance therapy with long-acting bronchodilators should be started as soon as possible before discharge from the hospital
- Respiratory support
 - Oxygen therapy is a key component of inpatient treatment of an exacerbation
 - Titrated to maintain saturation of 88-92%

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Management of COPD Exacerbations

- The strongest predictor of a patient's future exacerbation risk is the number of exacerbations they have experienced in the previous year
- Prevention of future exacerbations
 - Evaluate maintenance therapy
 - Reassess inhaler technique
 - Ensure understanding of acute medications
 - Steroids and/or antibiotics
 - Assess comorbidities
 - Follow-up

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COPD and Comorbidities

- COPD often coincides with other diseases that may play an important role in the progression of the patient's pulmonary disease
 - Cardiovascular disease
 - Osteoporosis
 - Depression and/or anxiety
 - Lung cancer
 - Metabolic syndrome and diabetes
 - GERD
 - Obstructive sleep apnea

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COPD and Comorbidities

- COPD and cardiovascular disease
 - Hypertension
 - Likely the most frequent comorbidity in COPD
 - Heart failure
 - Selective β_1 -blockers should be used
 - Arrhythmias
 - Ex. atrial fibrillation: use caution with short-acting β_2 -agonists and theophylline
 - Ischemic heart disease
 - Peripheral heart disease

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COPD and Comorbidities

- Many COPD patients face multiple-morbidity
 - 2 or more chronic conditions
- Signs and symptoms may overlap between multiple disease states
- When patients have other comorbidities, treatment should be simplified to minimize polypharmacy

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Key Points

- COPD is an common, preventable, treatable disease characterized by persistent respiratory symptoms and airflow limitation
 - Symptoms include dyspnea, cough, and sputum production
 - Main risk factor is smoking
- There are several medications available to help treat both stable disease and COPD exacerbations
 - Treatment should be initiated and escalated based on symptoms and exacerbation risk

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