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PHARMACY CONTINUING EDUCATION FROM WF PROFESSIONAL ASSOCIATES

"Review COPD: Therapeutic Options"

February 2016

Chronic obstructive pulmonary disease (COPD) is a term used to describe a group of progressive, chronic, debilitating, noncontagious, and irreversible pulmonary inflammatory diseases characterized by obstruction of airflow in the lungs thereby making breathing difficult. In the U.S. the term refers to two disorders: emphysema and chronic bronchitis. However, in some medical circles refractory bronchial asthma is included. In this lesson we discuss significant therapeutic options.

Pharmacists will be able to:

1. Describe the breathing process & how it relates to COPD.
2. Illustrate the prevalence of COPD.
3. List contributing factors that contribute to COPD.
4. List symptoms associated with COPD.
5. Discuss common therapeutic agents used to treat COPD.
6. List side effects associated with common drugs for COPD.

Technicians will be able to:

1. List drugs used to treat COPD.
2. Describe side effects associated with common COPD drugs.

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BACKGROUND

Chronic obstructive pulmonary disease (COPD) is a term used to describe a group of progressive, chronic, debilitating, noncontagious, and irreversible pulmonary inflammatory diseases characterized by obstruction of airflow in the lungs thereby making breathing difficult. In the U.S. the term refers to two disorders: **emphysema** and **chronic bronchitis**. However, in some medical circles refractory bronchial asthma is included.

Emphysema and **chronic bronchitis** show significant overlapping in etiology, symptoms and treatment. The main distinguishing features between the two, is that emphysema is accompanied by irreversible loss of elasticity and destruction as well as distention of the connective tissue supporting the alveolar sacs. This leads to air trapping and fewer healthy air sacs and blood capillaries that supply oxygen. Emphysema is believed to be due to the action of the proteolytic enzyme neutrophil elastase on the elastic tissue of the normal lungs. The enzyme is normally inhibited by alpha-antitrypsin (AAT). Deficiency of AAT allows the neutrophil elastase to cause structural changes in the lungs and development of early onset of emphysema (age 40 among cigarette smokers and 55 to 60 in nonsmokers).

Chronic bronchitis is an ongoing inflammation accompanied by edema in the bronchial mucosa as well as an increased production of a thick and sticky sputum and persistent productive cough that occurs daily for at least three months over a two year period. At the beginning the cough is mild and occurs in the morning upon arising. It is often dismissed as smoker's cough. With time this cough becomes more frequent and severe. Chronic bronchitis is associated with structural changes in the bronchial mucosa and hypertrophy of the mucus producing goblets cells. Gradually, obstruction of the air passages occurs and airflow is reduced. The bronchial mucosa appears irritated, hyperemic, and edematous. The mucociliary function becomes impaired. Thick sputum accumulates in the bronchial passages, causing irritation and intensification of cough.

PREVALENCE OF COPD

It is estimated that there are 11 million Americans who suffer from COPD and probably 24 million may have the disease and are not aware of it due to its insidious nature. It affects all states but the prevalence varies from one state to another. CDC analyzed data from the 2011 Behavioral Risk Factors Surveillance System (BRFSS)). The results indicate that 63% of adults had been informed by a physician that they had COPD; 67% of respondents indicated that they had been given a diagnostic breathing test; 64.2% stated that they experienced shortness of breath that detrimentally affected their quality of lives; 55% were taking at least one medication every day to manage COPD; and 43.2% had visited a physician for COPD symptoms in the last 12 months. Statewide, the prevalence ranged from 9.1% in Alabama and 9.3% in Kentucky to 3.9% in each of the states of Washington and Minnesota. The median prevalence in all states was 5.8%. Other sources gave higher estimates. COPD is the third leading cause of death in the U.S. and accounts for 4% of all deaths. About 3 million cases occur in the U.S. every year. CDC reports that the annual medical costs of COPD in the U.S. among adults 18 year of age and older were about $32.1 billion. This does not include $3.9 billion which was due to absenteeism. Projections for costs will reach $49 billion in 2020. CDC reported that 134,676 deaths occurred in the U.S. due to COPD.

RISK FACTORS

Long-term cigarette smoking is the most dominant risk factor that is associated with COPD. The more years a person smokes and the number of cigarettes smoked per day directly impact severity. Smoking accounts for 86-90% of COPD occurrences. Female smokers are nearly 13 times more likely to die from COPD than women who have never smoked. Likewise, male smokers are about 12 times as likely to die from COPD as men who never smoked. It has been speculated that the oxidants present in smoke play a role in triggering the initial and later phases of COPD. The oxidants tend to inactivate a_1-antitrypsin (AAT) and cause polymorphonuclear leukocytes to release proteolytic enzymes and to initiate a low-grade inflammation. Eventually smoking inactivates ciliary movement and causes atrophy and hyperplasm of the mucus-secreting goblets cells. Long-term exposure to bronchial irritants such as dust, fumes and other pollutants can also contribute to COPD.

People with bronchial asthma are at greater risk for developing COPD.

Occupations that require **long-term exposure to bronchial tree irritants** can trigger inflammation in the lungs and bronchial mucosa.

Familial or genetic factors such as deficiency in AAT may dispose the person to COPD.

Age is also a factor. COPD is an insidious and slowly developing disease. Early symptoms emerge at the age of 35-40 and increase in intensity as the patient gets older.

SYMPTOMS

Because COPD emerges slowly, symptoms often arise when there is significant damage to the lungs and bronchial airways. Left untreated, the symptoms worsen with time. These symptoms include:

1. Dyspnea (difficult breathing) especially following physical activity, but later on it may occur at rest. Both inhalation and exhalation become difficult
2. Wheezing due to passage of inhaled and exhaled air through narrowed bronchial airways due to bronchospasm, accumulation of sticky sputum, inflammation and edema.
3. Cough and increased production of sputum.
4. Chest tightness.
5. Cyanosis or blue discoloration of skin due to reduced amounts of oxygen in the blood and increased amounts of carbon dioxide as a result of reduced number of capillaries and loss of elasticity of the damaged alveolar sac walls.
6. Fatigue.
7. Cilia impairment.
8. In advanced cases, swelling in the ankles and feet, weight loss and tachycardia may occur. The severity of the symptoms depends mainly on the extent of lung damage.

DIAGNOSIS

Not everyone who experiences the above symptoms suffers from COPD, and not everyone who has COPD has these symptoms. There are other conditions that mimic COPD. Therefore,

diagnostic tests need to be performed for confirmation.

Physical examination as well as studying medical history and identifying symptoms experienced by the patient are important first steps toward diagnosis. In addition, the following tests will assist in confirmation:

1. **Lung Function Test:** This involves measuring the air that the patient can breathe in, and the speed at which the air is exhaled.
2. **High Resolution Computer Tomography:** This is a CT Scan that shows the images of the lungs and any abnormality that may be present.
3. **Chest X-Ray:** The usefulness of this test is that it helps in ruling out other lung disorders.
4. **Sputum examination** to confirm presence of neutrophil granulocytes.
5. **Measuring the oxygen level of circulating blood** in a sample taken from an artery. Results of the test will determine the need for oxygen therapy.

TREATMENT

COPD has no cure and currently there are no methods of treatment that reverse the damage to the lungs and bronchial airways. With proper care, use of medications, and lifestyle changes, symptoms can be controlled. The progress of the disease can be slowed, thereby, improving quality of life. Treatment is generally aimed at:

1. Alleviation of symptoms.
2. Reduction of progress of the disease.
3. Prevention of complications.
4. Improving general health by eating healthy foods, appropriate exercising, and avoidance of physical exertion.

Treatment consists of two parts: (1) **use of medications**, and (2) **lifestyle change**.

USE OF MEDICATIONS

There are a number of drug categories that are used in the treatment of COPD:

1. **Short and long-acting bronchodilators (SABAs and LABAs)**
2. **Long-acting muscarinic antagonists (LAMAs)**
3. **Phosphodiesterase-4**
4. **Corticosteroids (inhaled and oral)**
5. **Xanthine derivatives**
6. **Antibiotics**
7. **Oxygen Therapy**

SHORT AND LONG-ACTING BRONCHODILATORS

Short-acting beta$_2$-adrenergic agonists (SABAs)

These medications are used to achieve quick relief from sudden symptoms such as shortness of breath, coughing and bronchospasms. The meds are available orally, as metered-dose inhalers, or as liquids to be administered by means of a nebulizer. It has been theorized that beta$_2$-adrenergic agonists stimulate the production of cyclic adenosine-3,5 monophosphate

(cAMP) by activation of the enzyme, adenyl cyclase. The increased level of AMP enhances the activity of cyclic AMP-dependent protein, kinase A, which reduces the intracellular calcium concentration, resulting in relaxation of the bronchial airways and inhibition of the release of chemical mediators from the mast cell of the bronchial mucosa. Their action lasts from 4-6 hours.

Albuterol was 1st marketed in 1968 and approved for use in the U.S. in 1982. It acts on the $Beta_2$-adrenergic receptors of the bronchial cell membrane. It acts directly on the bronchial smooth muscles to cause dilation. Even though $Beta_2$ adrenergic receptors are predominant on the bronchial smooth muscles, there are some $Beta_2$ adrenergic receptors in some cardiovascular areas causing unwanted effects such as increased heart rate. Albuterol has lesser effects on the $Beta_2$ adrenergic receptors of the heart. Adverse effects of albuterol include tremor, anxiety, bradycardia, headache, dry mouth, insomnia and flushing.

Levobuterol has similar mechanism of action, side effects and uses as albuterol and other SABAs.

Terbutaline has similar mechanism of action, side effects and uses as albuterol and other SABAs.

Short-acting $beta_2$-adrenergic agonists (SABAs)

As the name implies, they differ from SABAs in the longer duration of action. They are used to prevent COPD symptoms and as maintenance therapy in moderate to severe symptoms. LABAs are not recommended for acute or sudden symptoms as their onset is longer than that of SABAs. They can be used as monotherapy or in combination with corticosteroids like beclomethasone dipropionate or fluticasone propionate. LABAs may increase the risk of asthma-related hospitalization in children and adolescents. They also may increase the risk of asthma related deaths. Increased risk of deaths in COPD patients has not been confirmed. The FDA has warned that the use of LABAs could lead to worsening of wheezing in some patients. Side effects of LABAs include bradycardia, headache, tremor, insomnia, dry mouth and nausea.

Vilanterol is a LABA which was approved by the FDA in 2013 for use in combination with fluticasone furoate in the treatment of COPD.

Furmoterol has duration of action up to 12 hours. It is usually administered with corticosteroids such as fluticasone and budesonide. It is available as a dry-powder inhaler, a metered-dose inhaler, an oral tablet and an inhalation solution. Furmoterol in combination with budesonide was approved by the FDA in 2009 for treating COPD. It is indicated only as a maintenance medication.

Salmeterol is available as a dry powder inhaler. It is usually used with corticosteroids such as beclomethasone.

Indacaterol is an inhaled ultra-long-acting $beta_2$ adrenergic agonist that is taken once daily for maintenance therapy, and lasts up to twelve hours. It is delivered as an aerosol formulation by means of a dry powder inhaler. The FDA approved its use in 2011. It is available also in combination with glycopyrronium, a LAMA, as an inhale.

Long-acting muscarinic antagonists (LAMAs)

Formally known as anticholinergics, they act by blocking activity of the muscarinic acetylcholine receptor. They are capable of dilating the airways. Atropine is not used due to its side effects.

Ipratropium when administered in a metered-dose inhaler, relaxes the bronchial passages. It is available in oral aerosol and in solution for nebulizers. Like other LAMAs, it acts as a nonselective competitive antagonist at the muscarinic receptor sites in the bronchial tree. As a result it relaxes the smooth muscles of the bronchial tree and bronchioles. When inhaled it does not cause any appreciable change in heart rate, rhythm and blood pressure. Side effects resemble those of anticholinergics, but minimally. They include dry mouth, tachycardia, nausea, and headache.

Umeclidinium is a LAMA that is usually administered by inhalation. The FDA approved its use in 2013 in combination with vilanterol. Side effects include anaphylaxis, swelling of lips, tongue or throat, rash and urticaria. Like most inhaled drugs, it may cause paradoxical bronchospasm. If any of these adverse effects occur, therapy must be discontinued.

Tiotropium Like the LAMAs, (except for aclidinium), has duration of action up to 24 hours when used once daily. Tiotropium is administered by inhalation. Side effects include dry mouth, sinusitis, pharyngitis, chest pain, blurred vision, dizziness and cough. Tiotropium is contraindicated in the presence of glaucoma. It comes as a capsule to be used with a specially designed inhaler.

Aclidinium is administered using a preloaded, metered dose dry powder inhaler. It was approved in the U.S. in 2012 as a maintenance treatment for COPD. It has similar actions and adverse effects as other LAMAs.

Long-acting inhibitors of the enzyme PDE-4

Roflumilast is a selective long-acting inhibitor of the enzyme phosphodiesterase-4 (PDE-4) which causes hydrolysis of cyclic adenosine monophosphate (cAMP) within the immune cells and cells in the CNS. By inhibiting PDE-4 the level of cAMP, remains normal. The drug is contraindicated in the presence of liver impairment and should be used with caution in cases of depression. Adverse effects include weight loss, nausea, vomiting, insomnia, anxiety, depression, and mood changes. Roflumilast should not be used with cytochrome P450 enzyme inducers.

Corticosteroids used for COPD are available in tablet, oral solution and inhaled form. They are administered in combination with beta$_2$-adrenergic agonists. Orally taken corticosteroids such as methylprednisolone are intended for moderate to severe exacerbation of COPD. Because of the adverse effect of long-term use, oral corticosteroids are given for a few days to prevent the intensification of flare-ups. Side effects include weight gain, increased blood pressure, diabetes, osteoporosis, cataracts, suppression of the adrenal gland, and increased susceptibility to infections. Inhaled corticosteroids such as beclomethasone, budesonide, flunisolide, fluticasone and mometasone are used to manage stable symptoms or symptoms that gradually, but slowly, get worse. Examples of corticosteroids in combination with LABAs include budesonide and furmoterol, fluticasone and salmeterol, fluticasone and vilanterol. Systemic absorption is minimal compared to orally administered forms. Inhaled corticosteroids relieve COPD symptoms by dilating the air passages and reducing the inflammation and swelling in the bronchial airways. In spite of the popularity of inhaled corticosteroids, questions have been raised as to their effectiveness. Adverse effects include nasopharyngitis, dysphonia, oral candidiasis and cough.

Beclomethasone dipropionate is a prodrug of the free form of beclomethasone. It is designed to be inhaled. It is available as a pressurized, metered-dose aerosol for oral inhalation only. Like other corticosteroid inhalers, it acts directly in the lungs resulting in reduction of inflammation, swelling, and irritation. These products are not intended for use in the relief of acute or sudden exacerbation (not a rescue medication). Their action is slow and may begin in 24 hours. Full

effect is achieved in 1 to 4 weeks. The patient should be advised by the pharmacist as to the proper use of these devices. The canisters should not be used close to an open flame. The label usually states the number of puffs each inhaler contains. It is advised that the patient needs to keep track of the number of puffs that have been used. Side effects include allergies, swelling of tongue and lips, sore throat, hoarseness and headache.

Budesonide is available as a powder to be inhaled or as a suspension to be inhaled by mouth using a specially designed nebulizer that breaks the suspension into a mist. It is also available as powder, solution, aerosol powder and aerosol liquid, which is intended to be used as a nasal spray for allergic rhinitis.

Fluticasone propionate is used as a powder or aerosol inhalation.

Mometasone is available as a spray to be inhaled through the nose to relieve allergies.

Xanthine derivatives include aminophylline and theophylline

These medications improve breathing via bronchodilation. To be effective, aminophylline must be converted to theophylline. Both act by inhibiting mast cell degranulation and release of histamine and other chemical mediators. They are used for COPD maintenance therapy because they relieve exacerbation. Adverse effects include CNS stimulation, cardiac palpitations, flushing, diuresis, and abdominal discomfort. They are available in tablets, capsules and solution.

Antibiotics

COPD patients are prone to bronchial infections. In the presence of infection a broad spectrum antibiotic, especially one that is effective against lactamase-producing microorganisms, may be given for a 7-10 day course. This may be repeated at the first sign of recurrent bronchial infection or sputum purulence.

Oxygen therapy

This is indicated if tests show that oxygen concentration in the blood is unsatisfactory. For home use the patient may rely on stationary large oxygen tanks. The oxygen is provided in compressed or liquefied form. Some patients use an electric device called an oxygen concentrator which is capable of concentrating the oxygen in the air and at the same time removing other gases. This method is relatively inexpensive, but the device generates considerable heat. Caution must be exercised to avoid open flames.

LIFE STYLE CHANGES

To help in the management of COPD, there are certain life-style changes that need to be suggested.

a. The top priority is to **stop smoking**.

b. **Avoidance of lung irritants** such as pollutants, dust and fumes.

c. Eating **good, healthy and nutritious food**. Such measures can strengthen the immune system. COPD patients frequently do not eat adequate quantities of food which can aggravate the symptoms. Health providers may recommend a plan that fits the patient's need, and also prescribe nutritional supplements. Underweight patients should eat healthy high calorie meals. Being overweight makes breathing more difficult, thus a plan

should be developed that will lead to weight loss.

d. Pulmonary rehabilitation programs, which include exercise training and breathing techniques, help provide relief from shortness of breath. Respiratory therapists can design a rehabilitation program that can keep the patient active and physically fit.

SUMMARY

COPD is a group of progressive, chronic, debilitating, inflammatory diseases characterized by obstructing airflow in the lungs and other parts of the bronchial airways. Such obstruction makes breathing and gas exchange difficult and deficient. There is no cure for COPD, but there are medications that may slow progress of the disease and relieve or reduce the symptoms. The disease is common and can be fatal. The main causes are tobacco, inhaling lung irritants such as dust, pollutants, and fumes, and exposure to second hand smoke. Medications used in the treatment of COPD include bronchodilators and anti-inflammatory agents.

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1. Does the program meet the learning objectives?
   - Describe the breathing process & how it relates to COPD — YES NO
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   - List factors that contribute to COPD — YES NO
   - List symptoms associated with COPD — YES NO
   - Discuss common therapies used to treat COPD — YES NO
   - List side effects associated with common drugs for COPD — YES NO
2. Was the program independent & non-commercial — YES NO

	Low Relevance						Very Relevant
3. Relevance of topic	1	2	3	4	5	6	7

4. What did you like most about this lesson?_____
5. What did you like least about this lesson?_____

Please Mark the Correct Answer(s)

1. **Which of these is true about COPD?**
   A. Curable disease
   B. Irreversible
   C. Can be prevented by immunization
   D. Contagious
2. **Gas exchange occurs in the:**
   A. Trachea B. Goblet cells
   C. Pharynx D. Alveolar sacs
3. **Which if these is true about the incidence of COPD in the U.S.?**
   A. 30 million sufferers in U.S.
   B. Median prevalence in all states is 9.3%
   C. About 3 million cases occur annually
   D. 10th highest cause of death in U.S.
4. **Which drug is considered a PDE-4 inhibitor?**
   A. Roflumilast B. Vilanterol
   C. Budesonide D. Albuterol
5. **Which of these has duration of up to 24 hours when used once daily?**
   A. Tiotropium B. Salmeterol
   C. Theophylline D. Aminophylline
6. **Which drug can cause dry mouth?**
   A. Methylprednisolone B. Ipratropium
   C. Terbutaline D. Corticosteroids
7. **Which drug is an ultra long-acting beta$_2$ adrenergic agonist?**
   A. Furmoterol B. Levobuterol
   C. Indacaterol D. Salmeterol
8. **Theophylline is:**
   A. Capable of preventing mast cell degeneration
   B. Capable of producing CNS depression
   C. Used mainly to treat sudden COPD attack
   D. Used as an inhaler
9. **Corticosteroids:**
   A. Are used orally for maintenance therapy of COPD
   B. Are potent bronchodilators
   C. Are employed only as monotherapy
   D. May be used in combination with LABAs
10. **Beta$_2$ adrenergic agonists act by:**
    A. Suppressing cAMP
    B. Stimulating the production of cAMP
    C. Releasing histamine from mast cells
    D. Reversing damage to bronchial mucosa

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