A Breath of Fresh Air?
An update of novel inhalers used for the treatment of asthma and COPD

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Disclosure

- I have no actual or potential conflicts of interest associated with this presentation or products mentioned within.

Objectives

Pharmacists:
- Review indications and dosing for new inhalers in the treatment of asthma/COPD based on current primary literature
- Identify patient-specific factors which contribute to non-adherence with current inhaler devices
- Design a therapeutic treatment regimen for patients at high risk of non-adherence
- Demonstrate proper use of inhaler devices and counseling techniques

Technicians:
- Identify patient-specific factors which contribute to non-adherence with current inhaler devices
- Review common side effects associated with various inhalers

Evolution of Inhalers

Right now you may be thinking...

WAIT
I'M CONFUSED

[Image of inhalers and Waht meme]
New Inhalers Approved

- Since July 2012, the FDA has approved 11 new inhalers/ or devices!
  - 4 Ellipta
  - 4 Respimat
  - 1 Respillick
  - 1 HFA
  - 1 Pressair

2012
- Turdoza® Pressia® (7/23/12)
- Anoro™ Ellipta® (12/18/13)

2013
- Turdoza® Pressia® (7/23/12)
- Anoro™ Ellipta® (12/18/13)
- Asmanex® HFA (4/25/14)
- Striverdi® Respimat (7/31/14)
- Amuly™ Ellipta® (8/20/14)
- Incrise™ Ellipta® (8/30/14)
- Spiriva® Respimat 2.5 mcg COPD (9/25/14)

2014
- Proair® Respiliq® (4/1/15)
- Breo® Ellipta® (4/30/15)
- Stiolto® Respimat (5/26/15)
- Spiriva® Respimat 1.25 mcg Asthma (9/15/15)
Inhalers by device/delivery system

**Dry Powder (DPI)**
- **Ellipta**
- **Anoro**
- **Arnuity**
- **Breo**
- **Incruse**
- **Pressair**
- **Turdoza**
- **Respiclick**
- **Proair**

**HFA**
- **Asmanex**

**Respimat**
- **Spiriva**
- **Stiolto**
- **Striverdi**

Inhalers by Medication Class

**Single**
- LABA
- LAMA
- ICS
- SABA

**Combination**
- LABA/LAMA
- LABA/ICS
- SABA/ICS

Hands on activity!!

**PLEASE MAKE GROUPS OF 4 AS WE WILL REVIEW THE NEW DEVICES!!**

**Ellipta Devices**

- **Storage:**
  - Must be thrown out once the dose reader reaches zero (at this point, no medicine is left) or 6 weeks after removing from foil pouch, whichever comes first

- **Maintenance**
  - Wipe mouthpiece with dry cloth or cotton swab as needed

- **Precautions**
  - Patients with severe milk-protein allergies should not use these devices as they may cause severe hypersensitivity reactions

- **Administration**
  - Open the inhaler cover by pushing mouthpiece back.
  - Once you hear a click, the mouthpiece is fully exposed.
  - Take a deep breath in and breathe out fully and completely, away from the inhaler.
  - Place the inhaler to your lips and form a tight seal around the mouthpiece. Take a deep breath in.
  - Make sure you do not block the air vent with your fingers.
  - Hold your breath for up to 10 seconds, or however long is comfortable.
  - Remove the inhaler from your mouth and breathe out.

- **Dose counter**
  - The Ellipta has a dose counter to indicate the number of doses left. When the dose counter turns red, it means you have limited medicine left (< 10 doses) and you need a refill.
**Anoro (umeclidinium/vilanterol)**

- Umeclidinium/vilanterol (LAMA + LABA) combination is indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, available for delivery via the Ellipta® device.
- Dosing
  - 62.5 mcg/25 mcg – 1 puff inhaled by mouth ONCE daily

**Clinical trials involving umeclidinium/vilanterol** were able to demonstrate significant improvement in pulmonary function and symptom reduction compared to placebo. Additionally, combination therapy of umeclidinium/vilanterol was significantly more effective than once-daily tiotropium, umeclidinium, and vilanterol monotherapies in lung function improvement.

- The German Institute for Quality and Efficiency in Health Care found that combination umeclidinium/vilanterol was not shown to demonstrate benefit over tiotropium.

- More specifically, in patients with moderate COPD and fewer than two exacerbations per year, umeclidinium/vilanterol did not show any differences in dyspnea and health-related quality of life compared to tiotropium.

**Arnuity (fluticasone furoate)**

- Fluticasone furoate (ICS) is indicated for maintenance treatment of patients with asthma age 12 years and older, available for delivery via the Ellipta® device.
- It is not indicated for acute bronchospasm.
- Dosing
  - 100 or 200 mcg inhaled by mouth once daily
  - Dose based on prior inhaled corticosteroid dose/use
  - Starting dose is 100 mcg inhaled by mouth once daily for mild-moderate persistent asthma

**Breo (fluticasone/vilanterol)**

- Combination fluticasone/vilanterol (ICS + LABA) is indicated for the long-term, once-daily maintenance treatment of airflow obstruction in patients with COPD and asthma (18 years of age or older).
- Fluticasone/vilanterol is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.
- Fluticasone/vilanterol is the first FDA-approved combination ICS/LABA to offer once-daily dosing for COPD. Currently, there are no head-to-head trials that have demonstrated superiority in the safety or efficacy of fluticasone compared to other ICS.
- Dosing
  - Asthma – 100/25 mcg or 200/25 mcg 1 puff inhaled by mouth once daily
  - COPD – 100/25 mcg 1 puff inhaled by mouth once daily

**Incruse (umeclidinium)**

- Umeclidinium is a long-acting muscarinic antagonist (LAMA) approved for long-term maintenance of lung function in patients with COPD.
- Umeclidinium is indicated for once daily maintenance of lung function in patients with COPD and received its indication based on clinical trials demonstrating improvements in FEV1 and FEV1/FVC in patients:
  - ≥40 years of age, currently smoking or with at least a 10-year pack history, a post-bronchodilator FEV1 <70% of expected, and a FEV1/FVC <70%
- Dosing
  - 62.5 mcg – 1 puff inhaled by mouth once daily
Incruse (umeclidinium)
- Study results included one randomized placebo-controlled, double-blind, parallel group trial. Time to rehospitalization and next COPD exacerbation were delayed by approximately 100 days with umeclidinium compared to placebo.
- Significant differences in time to COPD exacerbation, and time to rehospitalization were not observed between umeclidinium and the combination of umeclidinium and vilanterol.

Respinmat Devices
- Soft Mist
  - Spira
    - 1.25 mcg – Asthma
    - 2.5 mcg – COPD
  - Stiolt
  - Striverdi

Respinmat
- Administration
  - Priming required!
    - Point the inhaler towards the ground (away from your face) and press on the dose-release button continuously until you see a spray.
    - Repeat 3 more times for a total of 4 sprays towards the ground. Your inhaler is ready to use.
    - When you haven’t used it in more than 1 day, release 1 test spray towards the ground before using.
    - When you haven’t used it in more than 21 days, release 4 test sprays towards the ground before using.

Spiriva Respimat (tiotropium bromide)
- Tiotropium is an LAMA indicated for long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with COPD.
- There are 2 available strengths:
  - 1.25 mcg per 2 actuations – Asthma (Blue cap)
  - 2.5 mcg per 2 actuations – COPD (Aqua cap)

Stioltto Respimat (tiotropium/olodaterol)
- Tiotropium/olodaterol is a LAMA/LABA combination indicated for long-term maintenance of lung function in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.
- Tiotropium/olodaterol demonstrated improvement in forced expiratory volume (FEV1) and forced vital capacity (FVC) in patients:
  - 40 years of age or older, currently smoking or with at least a 10-year pack history, with moderate to severe COPD defined as a FEV1 of <80% predicted, and an FVC of <70%.
- Dosing:
  - 2.5 mcg/2.5 mcg – 2 puffs inhaled ONCE daily
**Stiolto Respimat (tiotropium/olodaterol)**

- Placebo-controlled trials remain the majority of the evidence supporting tiotropium/olodaterol with comparisons only available to the individual components of combination.
- Improvements in the primary outcome of exercise capacity by approximately 60 seconds were observed after tiotropium/olodaterol administration when compared to placebo.
- Improvements of 0.3 L in FEV1 were also observed when compared to placebo, however the long-term benefits of tiotropium/olodaterol are not available.

**Striverdi Respimat (olodaterol)**

- Olodaterol is a LABA indicated for long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with COPD.
- Compared to placebo, olodaterol was shown to improve lung function, as evaluated by FEV1 area under the curve from 0 to 3 hours, and trough FEV1. Olodaterol demonstrated long-term safety and efficacy in patients with moderate to very severe COPD compared to placebo. These patients were allowed to continue their “usual care” maintenance therapy other than other LABAs, including LAMAs, SAMAs, ICS, and methylxanthines.

**Turdoza Pressair (aclidinium bromide)**

- Aclidinium bromide is a LAMA indicated for long-term maintenance therapy for COPD-associated bronchospasm.
- Aclidinium received FDA approval after studies demonstrated significant improvements in lung function, health status, and nighttime COPD symptom reduction in COPD patients compared to placebo. Patients enrolled in the trial were greater than 40 years of age, current or former smokers with at least a 10 pack-year history with moderate to severe COPD (50% < FEV1 < 80% predicted and post-bronchodilator FEV1/FVC < 70%).
- Dosing
  - 400 µg TWICE daily

**Dosing**

- 400 µg TWICE daily

**Turdoza Pressair (aclidinium bromide)**

- Administration
  - Remove the mouthpiece cap from the inhaler.
  - Press the green button all the way, and then release your finger from the inhaler.
  - When a green bar appears, this means the dose is ready. If it is red, the dose isn’t ready quite yet.
  - Take a deep breath and breathe out completely away from inhaler.
  - Place your lips to the inhaler and form a seal around the mouthpiece. Take a deep, quick breath in until you hear a click. Hold your breath for roughly 10 seconds or however long is comfortable. Remove inhaler from your mouth and cover mouthpiece with dust cover.

**Dose indicator**

- Indicator will move into the red zone when there are 7 days left of medication.

**Patient education is a critical factor in the use and misuse of medication inhalers. Inhaler represents advanced technology that is considered so easy to use that many patients and clinicians do not receive adequate training in their use. Between 38% and 48% of patients do not use metered-dose inhalers or powder inhalers well enough to benefit from the prescribed medication, and 39–67% of nurses, doctors, and respiratory therapists are unable to adequately describe or perform critical steps for using inhalers. Of an estimated $25 billion spent for inhalers, annually $5–7 billion is wasted because of inhaler misuse. Reimbursement and teaching strategies to improve patient education could substantially reduce these wasted resources.**

*Respir Care 2005;50(10):1360 - 1374*
Improper Technique

- [https://www.youtube.com/watch?v=bDHEEVW42Y](https://www.youtube.com/watch?v=bDHEEVW42Y)
- Ask your patients
  - Can you show me how you are using the device?
  - Do you use a spacer?
  - Do you know how fast or slow to inhale the device?
  - Many devices now contain an auditory sound when inspiratory rate is appropriate.
- Do you understand why you are taking this medication?
  - [ie, maintenance vs rescue]

Cost

- Cost continues to remain one of the top reasons for non-adherence and this may lead to worsening of respiratory status and hospitalization.

Cost (cont.)

- Resources available
  - Manufacturer
    - Vouchers
      - Allow for 1-time fill to Medicare, uninsured and commercial insured patients
    - Medicare primary insurance (can't be processed with other insurance)
  - Coupons
    - Only can be used as SECONDARY insurance for cash and commercial insured individuals
  - Patient Assistance Programs (PAP)
    - Variable by manufacturer
    - Income dependent but patients can appeal due to financial hardship
    - May provide up to 1 year of medication at no charge

Dosing Schedule

- Adherence
  - Ask
    - Is the inhaler's administration schedule easy for the person to remember?
    - Does the patient take all of their medications once daily? Or multiple times per day?
    - How do you remember to take your medications?
    - Do you often forget to take your medication?

Storage

- Improper storage may lead to medication degradation, expiration and inadequate response leading to treatment failure
  - Ask
    - Where do you store your medication?
    - Do you keep your medications in an area which is either too hot, cold or humid?
    - How do you store your medication when traveling or going on a day trip?
Case studies

Let’s get back into groups to review the patient cases together!

Case #1

- MS is a 72 y/o F with a past medical history significant for Type 2 DM, HTN, COPD, OSA, hyperlipidemia, Parkinson’s disease and hyperthyroidism. She presents today to review her current inhaled maintenance inhalers. Upon further review she states that “they don’t work”. Below is a list of her current inhalers and how she takes them.
  - Spiriva Handihaler
    - 1 capsule once daily
  - Albuterol HFA
    - “as needed”
  - Foradil Aerolizer
    - 1 capsule twice daily

What questions do you have for her?
What potential barriers exist?
Can you recommend alternate therapies?
Would your recommendation change if she had memory impairment?

Case #2

- JR is a 64 y/o M presenting today for a hospital follow up after a recent COPD exacerbation. Past medical history significant for Type 2 DM with proliferative retinopathy OU, HTN, OA and RA. He reports that he recently started an inhaler about 3 weeks ago and found it difficult to use. He does not remember the names of his inhalers other than albuterol, only that he is instructed to take it once daily.

What questions do you have for her?
What potential barriers exist?
Can you recommend alternate therapies?
Would your recommendation change if he did not have insurance?
Would your recommendation change if he is turning 65 years old next week?

Questions??

Thank you!!

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