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Reevaluating the Standard of Care: A Look at Delivery Devices for COPD

**Announcer Introduction:**
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**Dr. Ramesh:**
When it comes to our patients with COPD, how do we go about deciding which delivery device is most appropriate? And when do we decide to make that change? How do we educate the patient on the appropriate use of the delivery devices? And how do we know that we have been successful?

Welcome to *Deep Breaths: Updates from CHEST*, on ReachMD. I am Dr. Navitha Ramesh, and joining me today to discuss nebulizer therapy for patients with COPD is Dr. Allen Blaivas, a pulmonologist in the Division of Pulmonary, Critical Care, and Sleep Medicine at the V.A. in New Jersey Healthcare System, and Clinical Assistant Professor at Rutgers New Jersey Medical School. Dr. Blaivas, welcome to the program.

**Dr. Blaivas:**
Thank you for having me, Dr. Ramesh.

**Dr. Ramesh:**
So, to get started today, Dr. Blaivas, let's start our discussion with what's new in GOLD 2023?

**Dr. Blaivas:**
That's an interesting question. They actually made some fairly decent changes both in terms of treatment and, even to start with, they tried to give a new definition of COPD, exactly how we focus on COPD. So, I'm going to actually quote what they said. I think it would be helpful just to highlight some things in the definition so we can really understand what they were driving at.

They said that COPD is a heterogeneous lung condition characterized by chronic respiratory symptoms, which include dyspnea, cough, sputum production exacerbations. And this could be due to abnormalities in the airways, cause basically, bronchitis and bronchiolitis and/or alveoli. So that means emphysema when they're talking about alveoli, and these can cause persistent, and often progressive airflow obstruction.

So what's nice about this definition is the focus on heterogeneity, that it's not one disease, not everybody is getting the same disease. And the other thing is that they really focused in on what the definition is, the symptoms that people experience. That's a new side to the definition, that we're really focusing on looking at the symptoms, even included as part of the definition and even define some relatively new categories of early types of COPD.

**Dr. Ramesh:**
That's great, Dr. Blaivas. So, the definition itself gives us more insight about the treatment. So, understanding the definition of COPD is very important. And GOLD did a great job on redefining the COPD definition.

Now from there, from the definition, moving on to the pharmacological therapy for stable COPD GOLD 2023 recommendations clearly mention that inhaled therapies are the standard of care in our patients with COPD, and a lot of emphasis on individualized therapy for our patients. What are your thoughts about that, Dr. Blaivas?

**Dr. Blaivas:**


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So when we talk about individualized therapy, I think it's worth going back to the GOLD groups where they kind of define, and especially in GOLD 2023, they did make some changes, some important changes which are worth discussing.

So looking at the group, like Group A which is relatively asymptomatic group mMRC 0 to 1, and a CAT score less than 10, in those patients, they're mostly recommending just using bronchodilators mostly short acting for when they're symptomatic. That was not changed, that recommendation did not change. In Group B, we have an mMRC of greater than or equal to 2, or a CAT score greater than or equal to 10. Again, the recommendations remain relatively the same, but there was a focus on using in those patients, not a single agent therapy. They were focusing on using a LABA/LAMA, because it's been shown that there's fairly high symptom burden when patient is started on a single agent. So, the recommendation was to really start with a LABA/LAMA in those groups.

And that extends into Group E, which is the new group. Very interesting the way they focused on defining Group E is because there used to be a Group C and D, as we're all familiar with, but now they changed it looking at mostly exacerbation. So, we'll always define Group C and D with the fact that it was symptoms in one group plus exacerbations, and then relatively asymptomatic, but still exacerbations. So, they took away the importance of symptoms, that group is defined as having two or more exacerbations per year or one severe exacerbation. So, Group E, the new group, is highlighting the importance of exacerbations.

And in those patients who are very symptomatic, particularly if they have more than 300 and eosinophils, or they have asthma, you could use LABA/LAMA, but you should also probably add ICS in those patients. That's also a relatively new recommendation from GOLD, then in those groups that have fairly high exacerbation burden plus eosinophils, or a history of asthma, it's certainly reasonable to use ICS.

**Dr. Ramesh:**
That's great, Dr. Blaivas. So, you know, we've established that inhaler therapy standard of care. So, based off of that, we know that there are several classes of aerosol devices available for COPD, such as our metered dose inhalers, dry powder inhalers, soft mist inhalers, and small volume nebulizers. In your experience, Dr. Blaivas, what do you feel are the pros and cons of these delivery devices?

**Dr. Blaivas:**
So in terms of each of the devices, we'll start with the MDI. The advantages of the MDI are pretty obvious. You know, they're small devices, they're portable, they're compact patients are pretty familiar with them, they deliver the treatment in very rapid time they're propelled, they have high ins. When they are self-propelled and because of that high inspiratory flow rates from the patient are not so important because they're basically being sprayed into the oropharynx, and hopefully down to the lung if the coordination is good. And they can be used with a spacer device to help with that coordination. The disadvantages as I've been dancing around is the coordination is really necessary for these devices. Even with a spacer, they're not so easy for patients to use. Patients often can't even figure out how to use the spacer and when it's appropriate to use it.

When we're talking about DPIs, the dry powder inhalers, advantages are similar to MDI that they're portable compact, you could take it with you, and they have a short treatment time, meaning you don't have to spend a lot of time trying to get the drug. The disadvantages are that those are the ones especially that need a high peak inspiratory flow rate, which in patients with COPD or neuromuscular diseases is often difficult for them to generate, they just don't have the strength, the muscle strength to get that drug in, and then that leads to oral pharyngeal deposition. And particularly with the ICS, with the inhaled corticosteroid, that's when a lot of the adverse events could occur in the mouth, when you get their oropharyngeal deposition.

The soft mist inhalers are relatively new on the market. They came in with a bang. But there are limited drug classes available in them. That's an obvious disadvantage. And a recent study shows that even though they're relatively easy to use, still, roughly 60 percent of patients still make errors when using them. The advantages are they're portable, much in the way of the MDI and the DPI, portable, compact, you take it with you. They do not require a high peak inspiratory flow rate because they're self-generated.

The small volume nebulizers that's the old standard, which we've been using in asthma and COPD for years. Patients like them. The advantage is that patient coordination is not needed. Anyone who's tried to use these in a patient, in a child, knows that you just put it on, and they can wear the mask and they don't need to do anything other than breathe. They do not require a high peak inspiratory flow rate in order to get the drug down. And the small size generally between 1 and 5 micrometers, goes straight down into the lungs. The disadvantages are that it's less portable and need some sort of a power source either to be plugged in or a battery, and they are definitely longer treatment times.

**Dr. Ramesh:**
Thank you, Dr. Blaivas, that's a very good comprehensive pros and cons of all our inhaler and nebulizer devices available.

As you had mentioned, you know, each one has its own advantages and disadvantages. For example, the soft mist inhalers do not have


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an ICS component to them. So that brings me to this question: What do you think is the role for inhaled corticosteroids in patients with COPD?

**Dr. Blaivas:**
So that's a great question which has really been bounced around for quite some time now in terms of the GOLD guidelines and other recommendations from other groups from ATS and other societies, really where ICS fits in. And the data is not 100 percent clear. As I mentioned before the GOLD guidelines, the new change was that patients who have eosinophils or asthma, it's totally reasonable to treat them with ICS in addition to the LABA/LAMA. But some new, more recent studies show that LABA/LAMA plus ICS so the long-acting beta agonist plus the long-acting muscarinic antagonists plus the inhaled corticosteroid together in what we term triple therapy, improves lung function, improves symptoms and general health status, and reduces exacerbations compared to with the LABA and the ICS LABA/LAMA, and LAMA monotherapy. That's what the GOLD guidelines said, and that was very good evidence that they had to support that.

And recent data even suggest that triple therapy versus fixed dose LAMA/LABA, there's benefits in mortality in symptomatic COPD patients with frequent or severe exacerbations. So, there's definitely a role for ICS. We're evolving in our thinking. And I think we will probably define a group where it's really helpful.

**Dr. Ramesh:**
For those just tuning in, you're listening to ReachMD. I'm Dr. Navitha Ramesh, and I'm speaking with Dr. Allen Blaivas about nebulizer therapy for COPD. So far, we have discussed about the latest GOLD 2023 recommendations for management of stable COPD patients and the various aerosol delivery devices available.

So Dr. Blaivas, When would you choose a nebulizer therapy for your COPD patient?

**Dr. Blaivas:**
So nebulizer would definitely be more appropriate in patients who can't use other devices. That's the obvious one. Patients who are cognitively impaired and they don't have help from a family member or somebody who could help them take their medications, the patients, as we mentioned, who have COPD or neuromuscular disease. And many patients with COPD also have some neuromuscular weakness due to their emphysema. And you know, the barrel chest that we see in COPD, so they can't generate sufficient peak inspiratory flow rates for the DPI, and even for some of the other meds, but particularly the DPIs, the dry powder inhalers. Patients who have difficulty with coordination because for those patients, it's not that easy. I don't know if you've ever used an inhaler. I personally have not, but I've used them with my kids, I've helped my kids do them. And it's not easy to coordinate the pumping and the breathing in, and then the patients really need to know that they have to do a breath hold. It's not enough just to spray it in, and then that's it. And as we know, many patients are not using it the correct way. We really have to emphasize as physicians that each time, we have to check the usage and figure out if they're using it, assess, teach them first and then assess and reassess at almost every visit if the technique is proper.

**Dr. Ramesh:**
Very well said, Dr. Blaivas. So there's a lot of emphasis now on shared decision-making for our patients with COPD and individualizing the therapy, as you had mentioned. So you know, not just what class of medication is recommended, it's also what's the cost of the medication, the availability, and the patient characteristics, as you had just mentioned, prior to deciding, you know, what aerosol devices to give our patients.

So I would like to ask one more question, Dr. Blaivas. So let's say you have a patient who has been stable on your current triple therapy, and now you're talking about de-escalating therapy. So how would you recommend we de-escalate therapy in stable COPD patients?

**Dr. Blaivas:**
So, I'll tell you, the ATS recommends that after one year without exacerbations, you should consider de-escalating. And the GOLD is definitely against initiation, as we've been talking about, mostly because of the repeated pneumonia risk. And patients, if you come in, let's say, patients might be seen by their primary care doctor who put them on, they put them on the LABA ICS. If they have low blood eosinophils, it's probably not appropriate which is really defined as less than 100 cells – of less than 100 eosinophils, those patients could probably be de-escalated. Let's say they were started on LABA ICS, and if you go back and their baseline wasn't over 300 or even 100 to 300, then you could probably take them off. And anyone with a history of mycobacterial infection probably should not be on these.

So, there's reasons to de-escalate. And those are the groups which you really want to look at de-escalating. And we also know that there could be some risk in terms of osteoporosis potentially. Again, this is not 100 percent clear. But some studies definitely showed that there is an osteoporotic risk. So those are the types of patients you should really focus on de-escalating.

**Dr. Ramesh:**


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Thank you, Dr. Blaivas. So it goes back to, you know, is your patient using your inhaler, how's the inhaler technique, making sure everything is taken care of prior to even altering the medications. And looking at the flip side, what is the harm of inhaled corticosteroids? Keeping that in mind all the time is important as well.

With those considerations in mind, I want to thank my guest, Dr. Allen Blaivas, for joining me in today's discussion. Dr. Blaivas, it was great speaking with you today.

**Dr. Blaivas:**
It was great speaking with you. Thank you for having me.

**Dr. Ramesh:**
Thank you. I'm Dr. Navitha Ramesh. Thank you for listening.

**Announcer Close:**
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