

COPD – A New Paradigm: Diagnosis and Treatment

Amen Sergew, MD

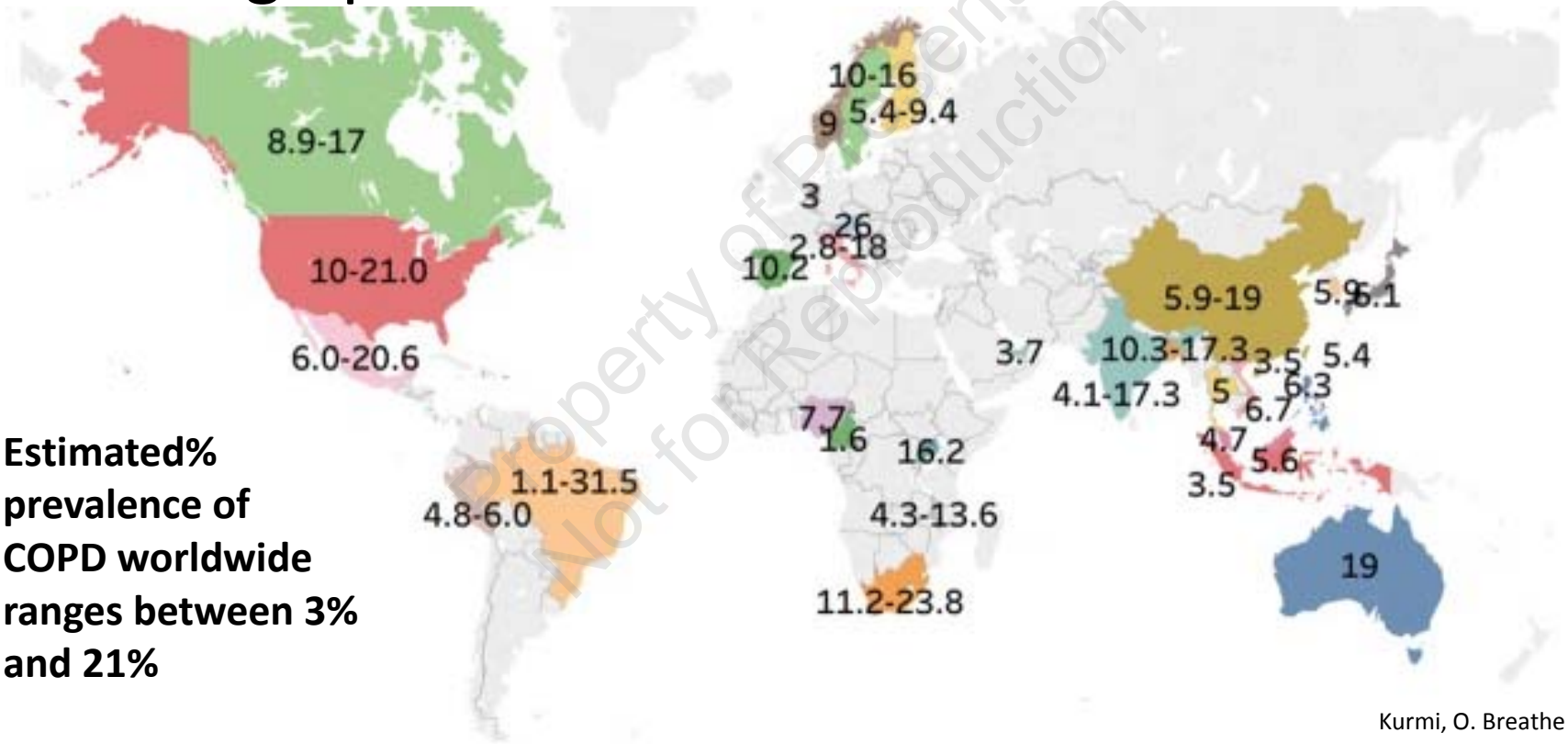
Disclosures

- Nothing to disclose

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Introduction

High prevalence of COPD worldwide



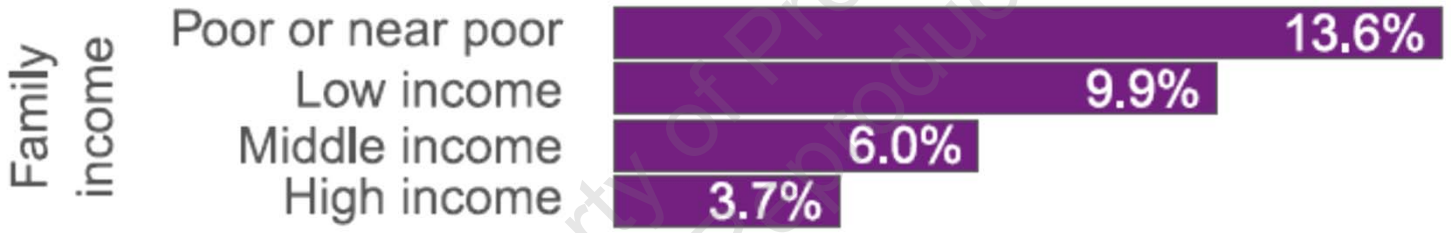
Estimated% prevalence of COPD worldwide ranges between 3% and 21%

Kurmi, O. Breathe 2019; 15

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Introduction

Highest prevalence in low income patients

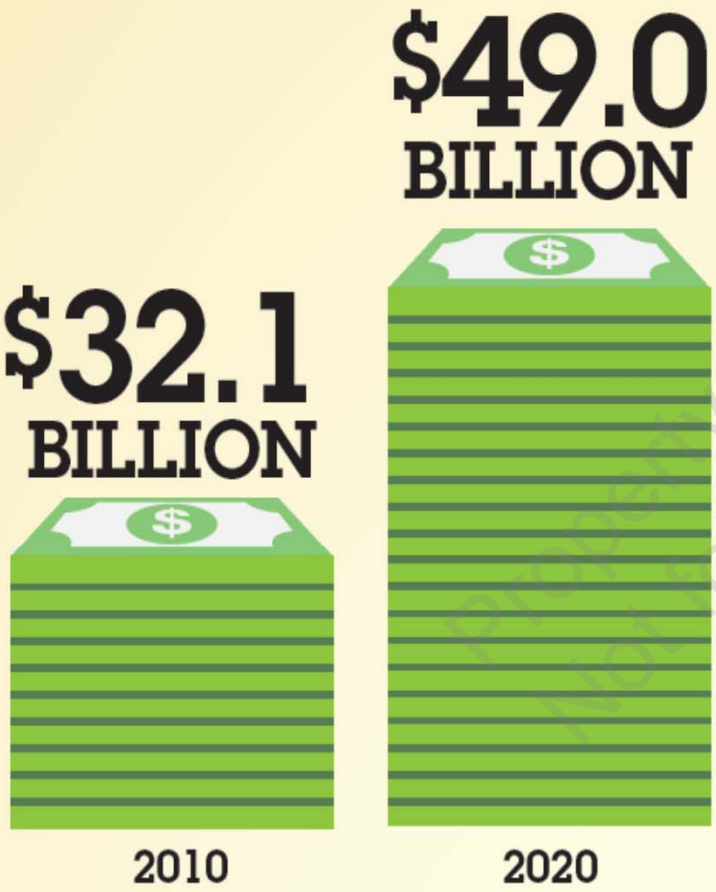


US Data from 2014-2015 on percent prevalence in adults age ≥ 40

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Biener, A. JAMA. 2019. 322; 7

COPD Costs

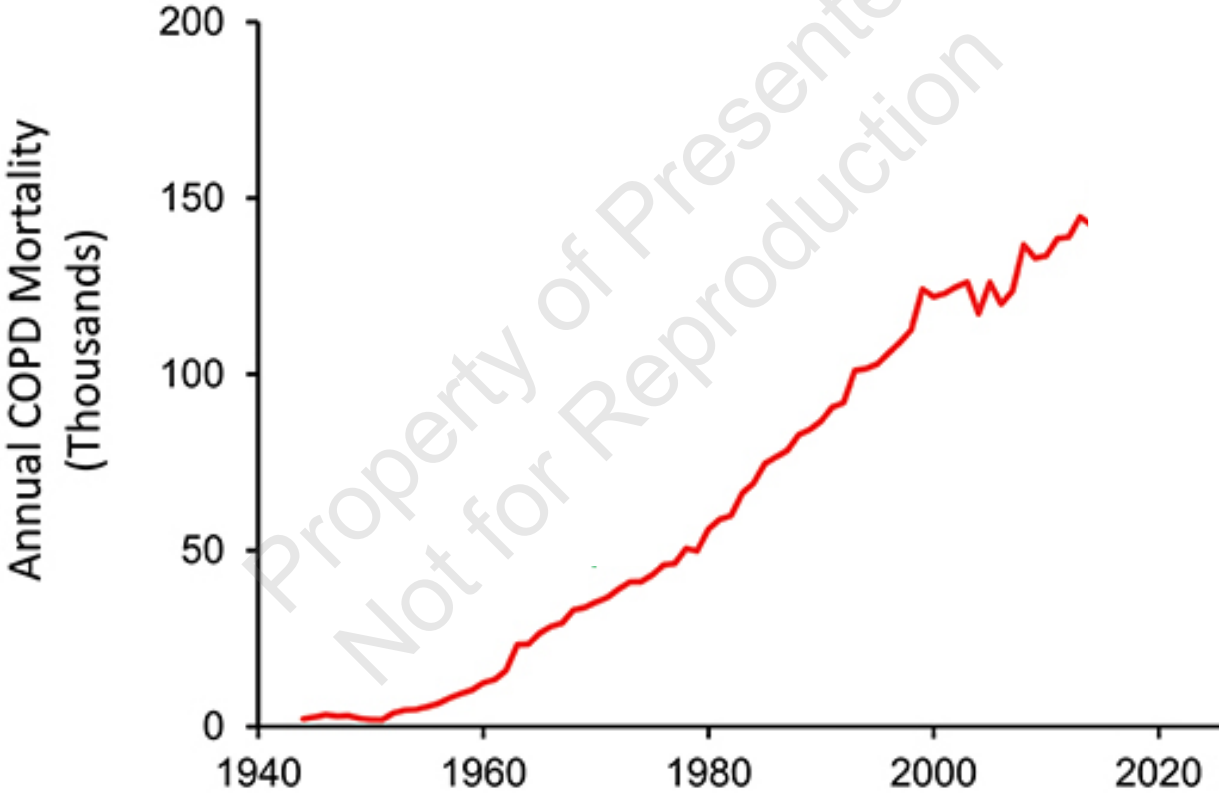


Costs attributable to having COPD were $32.1 billion in 2010 with a projected increase to $49.0 billion by 2020.

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www.cdc.gov/copd

Mortality from COPD in the US



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Crapo, J. Chronic Obstr Pulm Dis. 2019; 6(4)

Objectives

- Review current and emerging therapeutics in the treatment of COPD
- Discuss best practice approaches for initial assessment and management of COPD to improve symptoms and prevent exacerbations
- Describe patient-centered strategies for creating personalized treatment plans for COPD
- Other hot topics in COPD

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CASE #1: 69 year old man

HPI

- Shortness of breath x 2 years; still able to exercise 30 minutes a day
- Wheezing and chest tightness
- 2 Exacerbations in the past year
- Referred new to you

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MODIFIED MRC DYSPNEA SCALE[a]

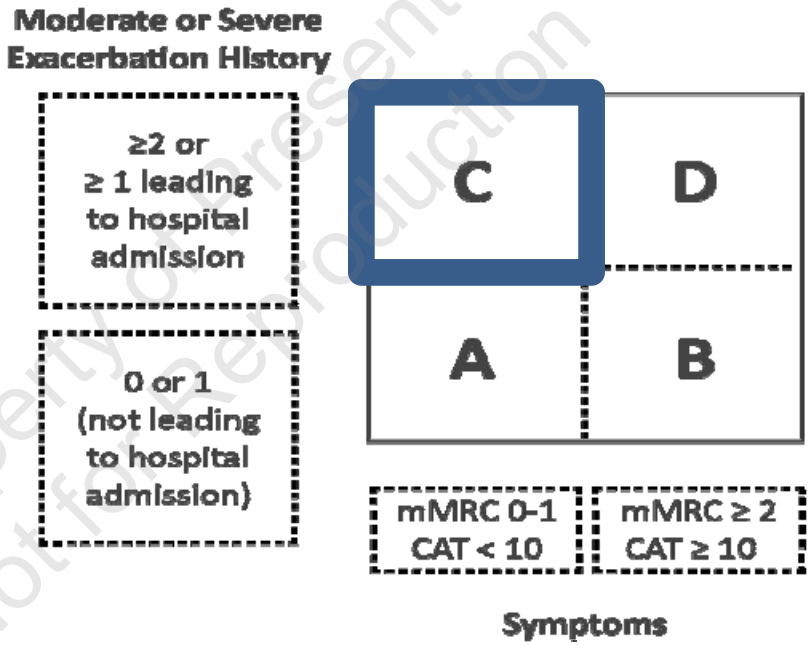
mMRC Grade 0.	I only get breathless with strenuous exercise.	☐
mMRC Grade 1.	I get short of breath when hurrying on the level or walking up a slight hill.	☐
mMRC Grade 2.	I walk slower than people of the same age on the level because of breathlessness, or I have to stop for breath when walking on my own pace on the level.	☐
mMRC Grade 3.	I stop for breath after walking about 100 meters or after a few minutes on the level.	☐
mMRC Grade 4.	I am too breathless to leave the house or I am breathless when dressing or undressing.	☐

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Fletcher CM. BMJ 1960; 2: 1662.

GOLD Group

Grade	FEV_1 (% predicted)
GOLD 1	≥ 80
GOLD 2	50-79
GOLD 3	30-49
GOLD 4	< 30



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You confirm he has COPD. What would you start:

a) ICS/LABA/LAMA
b) ICS/LABA
c) LABA
d) LAMA
e) LABA/LAMA

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ICS=inhaled corticosteroids; LABA=Long acting beta agonists; LAMA=Long acting anti-muscarinic

What would you start:

a) ICS/LABA/LAMA

b) ICS/LABA

c) LABA

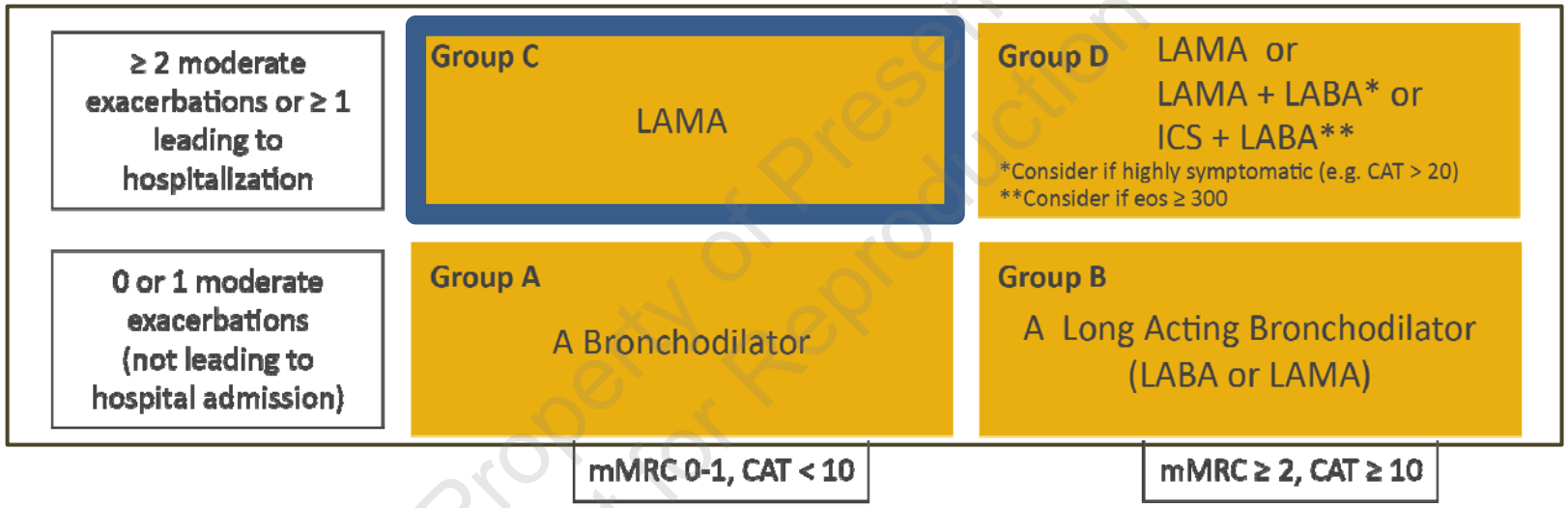
d) LAMA

e) LABA/LAMA

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ICS=inhaled corticosteroids; LABA=Long acting beta agonists; LAMA=Long acting anti-muscarinic

Initial Pharmacological Treatment = LAMA



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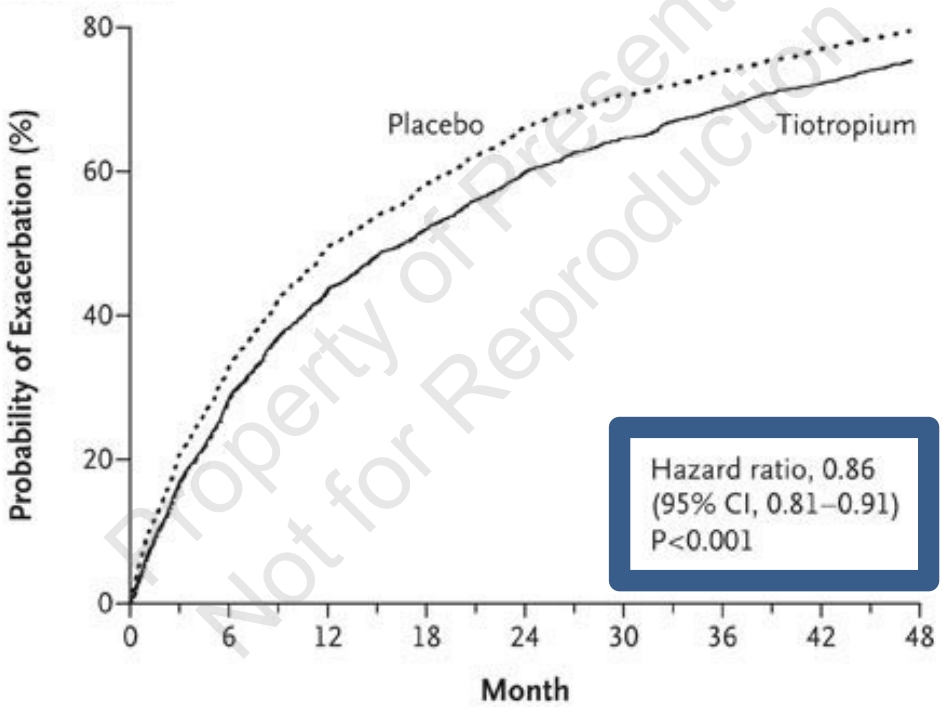
ICS=inhaled corticosteroids; LABA=Long acting beta agonists; LAMA=Long acting anti-muscarinic

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Tiotropium in COPD

UPLIFT Trial
N=5993

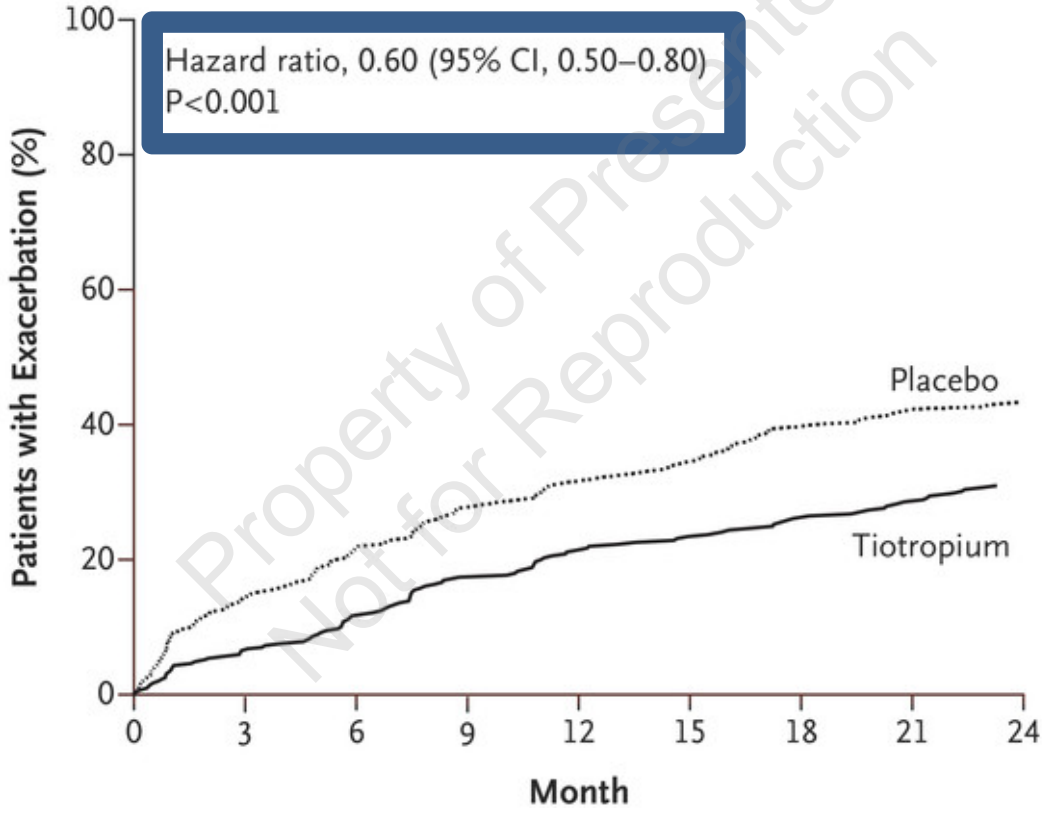
- **Improvements in quality of life scores**
- **No significant benefit in mortality**



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Tashkin. N Engl J Med 2008; 359 : 15

Tiotropium in Gold Stage 1 and 2



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N=841

Zhou, Y. N Engl J Med 2017; 377

Why not a LABA in a patient with exacerbations?

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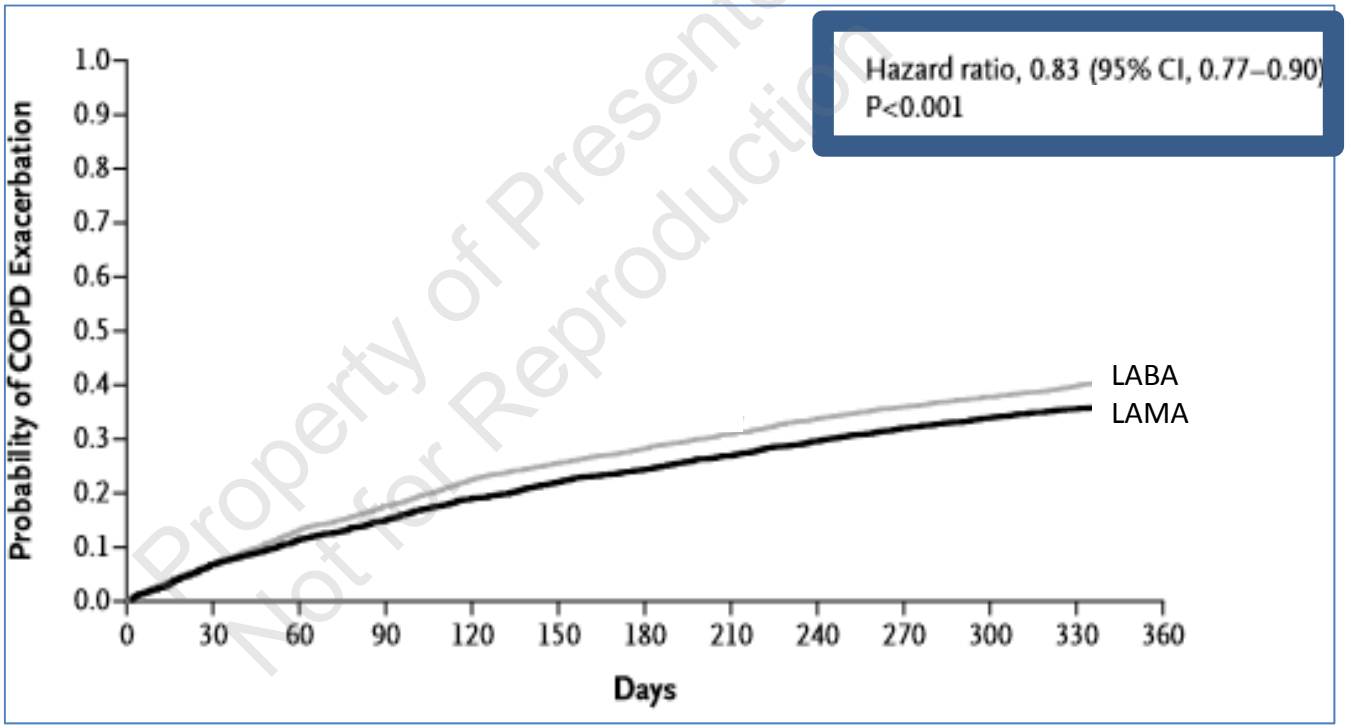
LAMA > LABA in patients with exacerbations

POET-COPD

- **Shorter time to first exacerbation**
- **Fewer moderate and severe exacerbations**

INVIGORATE

- **Longer time to first exacerbation**
- **Decrease rate of exacerbations**

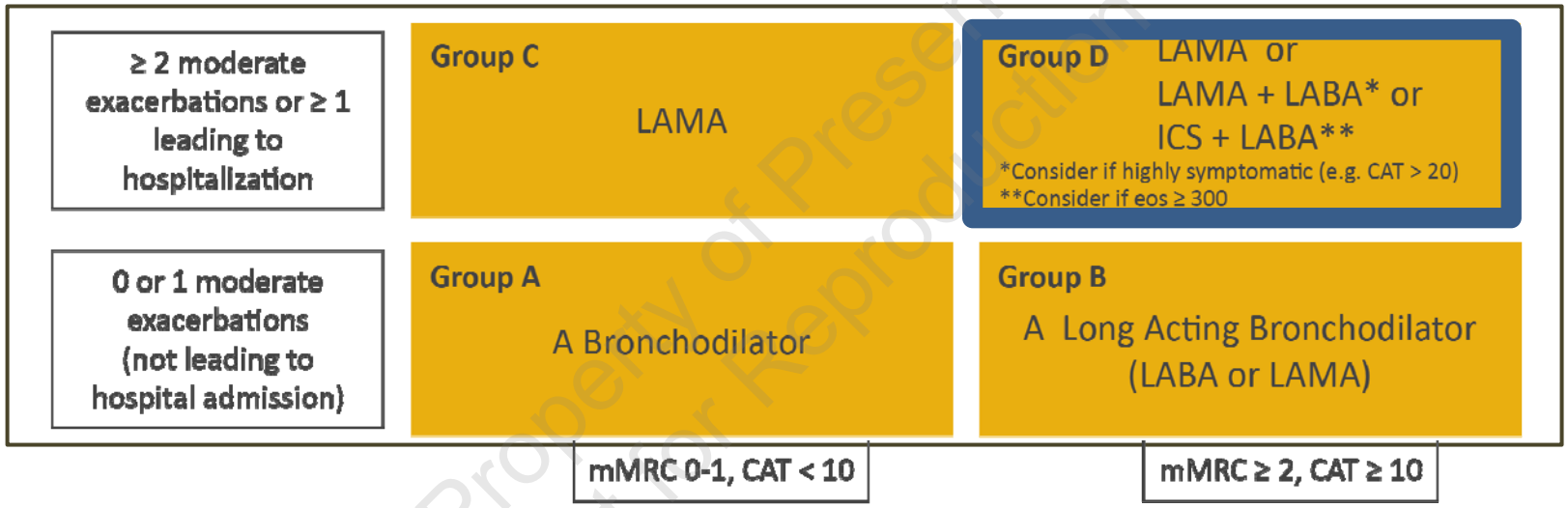


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LABA=Long acting beta agonists; LAMA=Long acting anti-muscarinic

Decramer. Lancer Respir Med 2013; 364 : 12
Vogelmeier. N Engl J Med 2011; 524 : 33

Initial Pharmacological Treatment



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ICS=inhaled corticosteroids; LABA=Long acting beta agonists; LAMA=Long acting anti-muscarinic

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LABA/LAMA versus LABA/ICS?

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ICS=inhaled corticosteroids; LABA=Long acting beta agonists; LAMA=Long acting anti-muscarinic

LABA/LAMA versus LABA/ICS

FLAME: Fewer exacerbations in LAMA/LABA

AFFIRM:

- No difference in dyspnea, rate of exacerbations
- LAMA/LABA higher FEV1 at 4 -12 -24 weeks

Real World Study:

- Similar exacerbation rates: LABA/ICS better if eos >6%
- LABA/ICS had more incidence of pneumonia

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ICS=inhaled corticosteroids; LABA=Long acting beta agonists; LAMA=Long acting anti-muscarinic

Wedzicha JA. NEJM 2016; 374
Vogelmeier C. Eur Resp J 2016; 48
Suissa S. Chest 2019; 155

When should you consider ICS when initiating therapy for COPD?

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ICS=inhaled corticosteroids

FACTORS TO CONSIDER WHEN INITIATING ICS TREATMENT

· STRONG SUPPORT ·

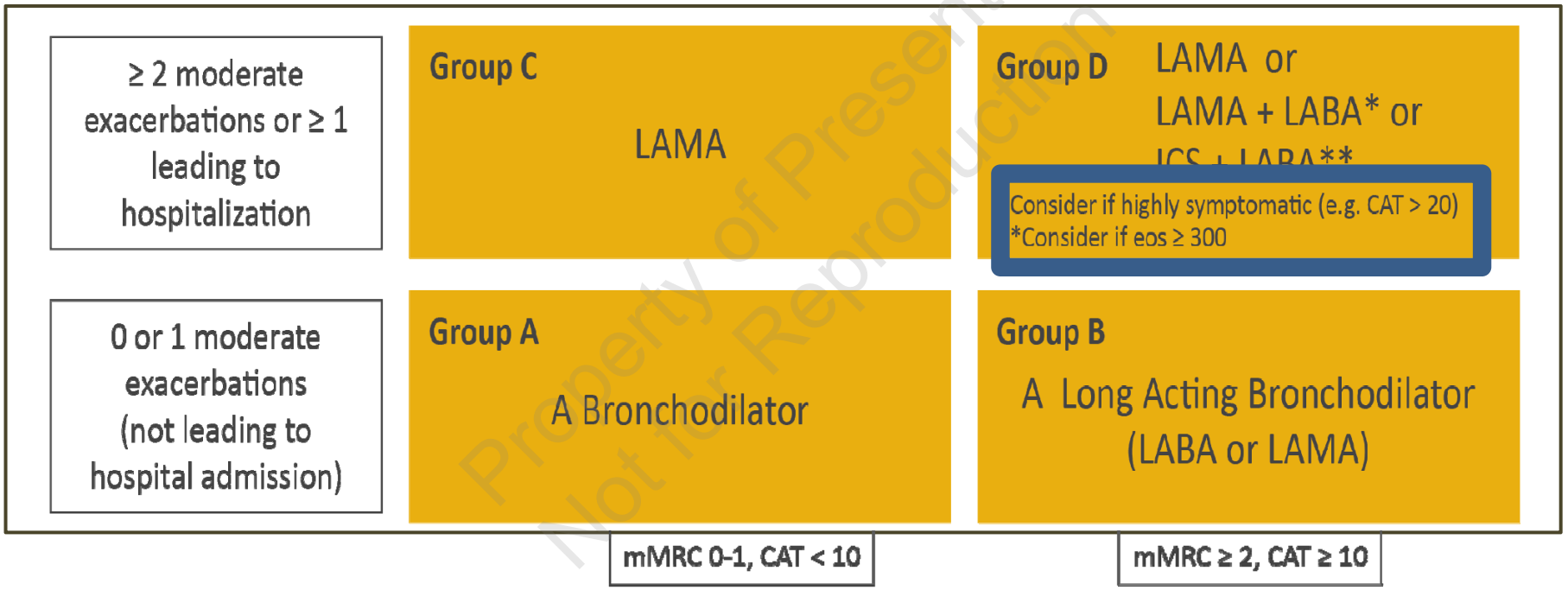
- History of hospitalization(s) for exacerbations of COPD#
- ≥ 2 moderate exacerbations of COPD per year#
- Blood eosinophils >300 cells/µL
- History of, or concomitant, asthma

ICS=inhaled corticosteroids

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Initial Pharmacological Treatment



ICS=inhaled corticosteroids; LABA=Long acting beta agonists; LAMA=Long acting anti-muscarinic

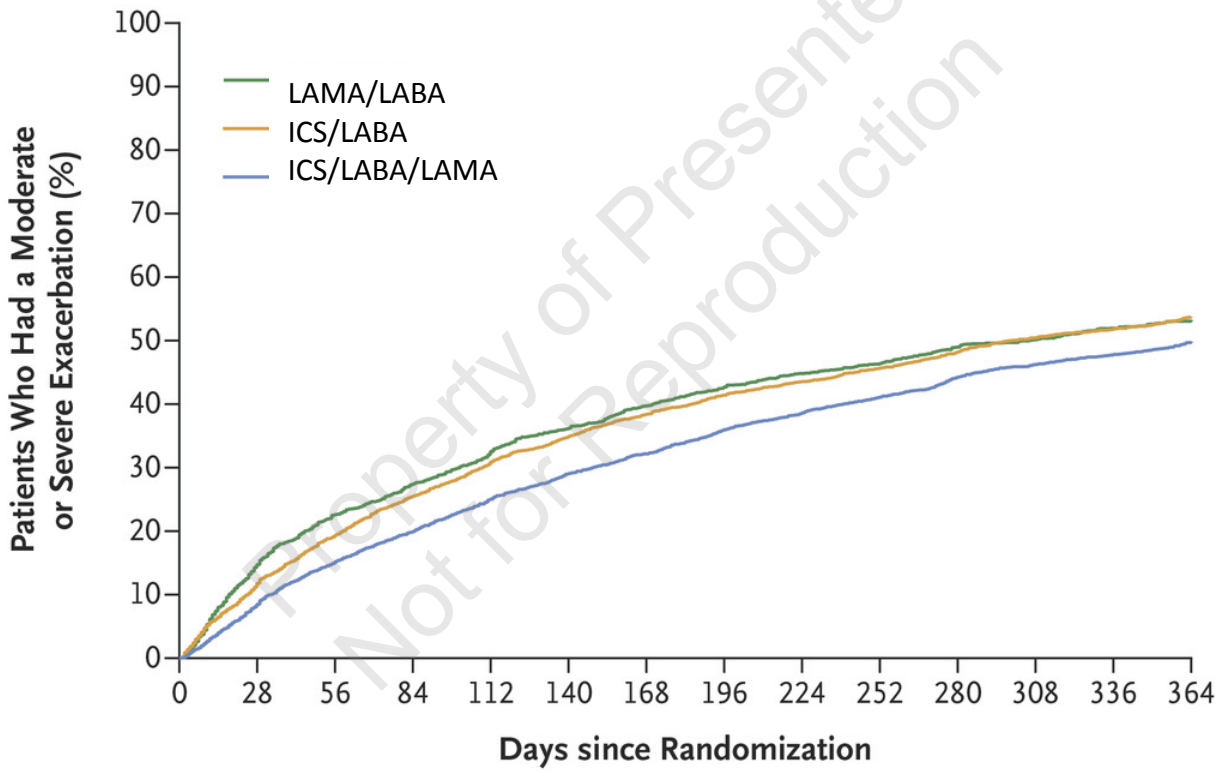
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When should you consider escalating therapy by adding an ICS?

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ICS=inhaled corticosteroids

Triple vs Dual Therapy: IMPACT Study

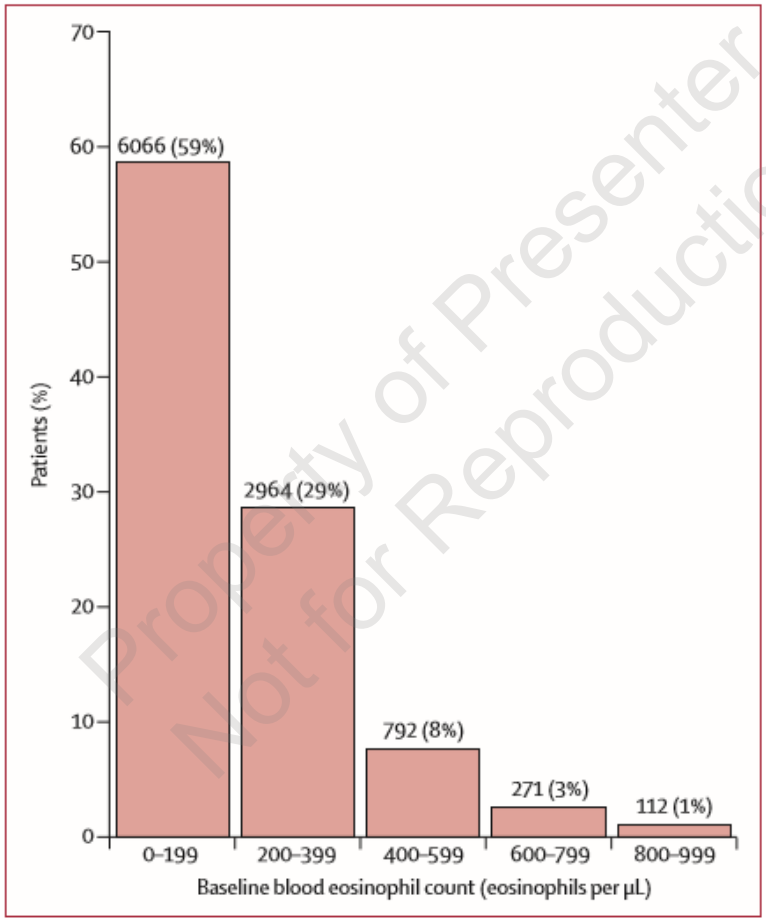


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ICS=inhaled corticosteroids; LABA=Long acting beta agonists; LAMA=Long acting anti-muscarinic

Lipson. N Engl J Med 2018; 378 : 18

Eosinophils and Treatment Response: IMPACT



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Pascoe S. Lancet Respir Med 2019; 7

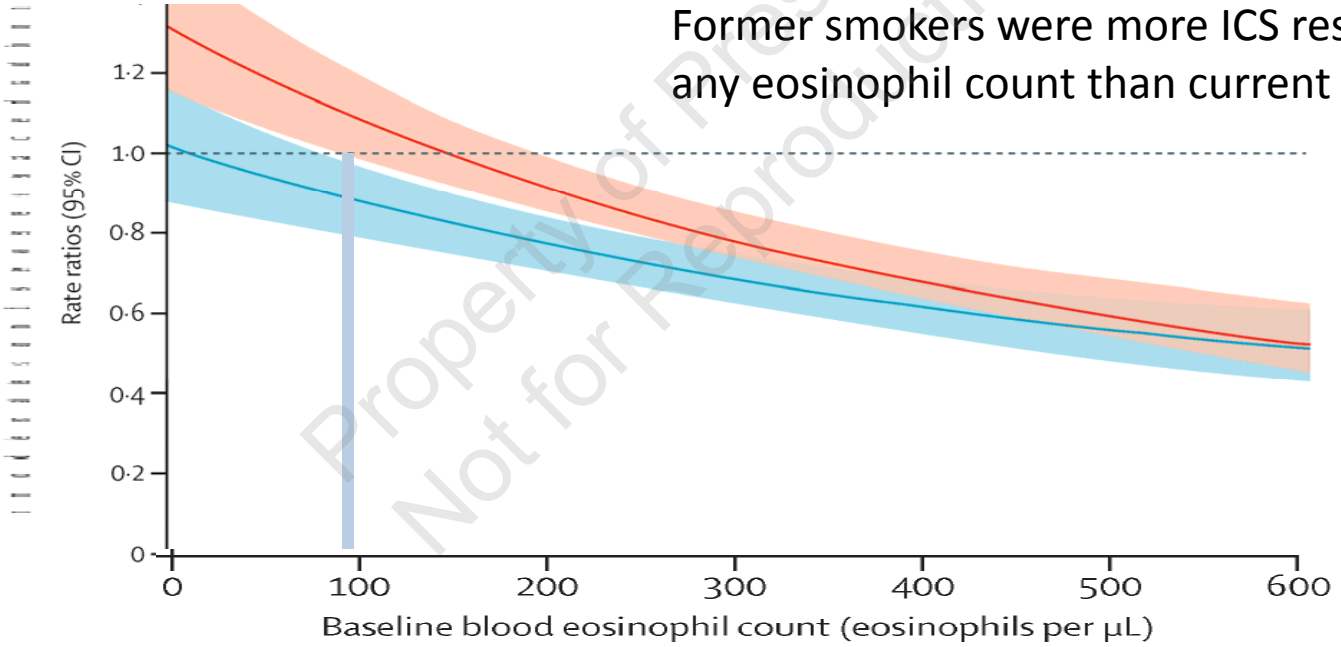
Eosinophils and Treatment Response: IMPACT

No difference between triple therapy and with LABA/LAMA at eosinophils counts less than 90

ICS/LABA/LAMA vs LABA/LAMA

ICS/LABA vs LAMA/LABA

Former smokers were more ICS responsive at any eosinophil count than current smokers.



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Pascoe S. Lancet Respir Med 2019; 7

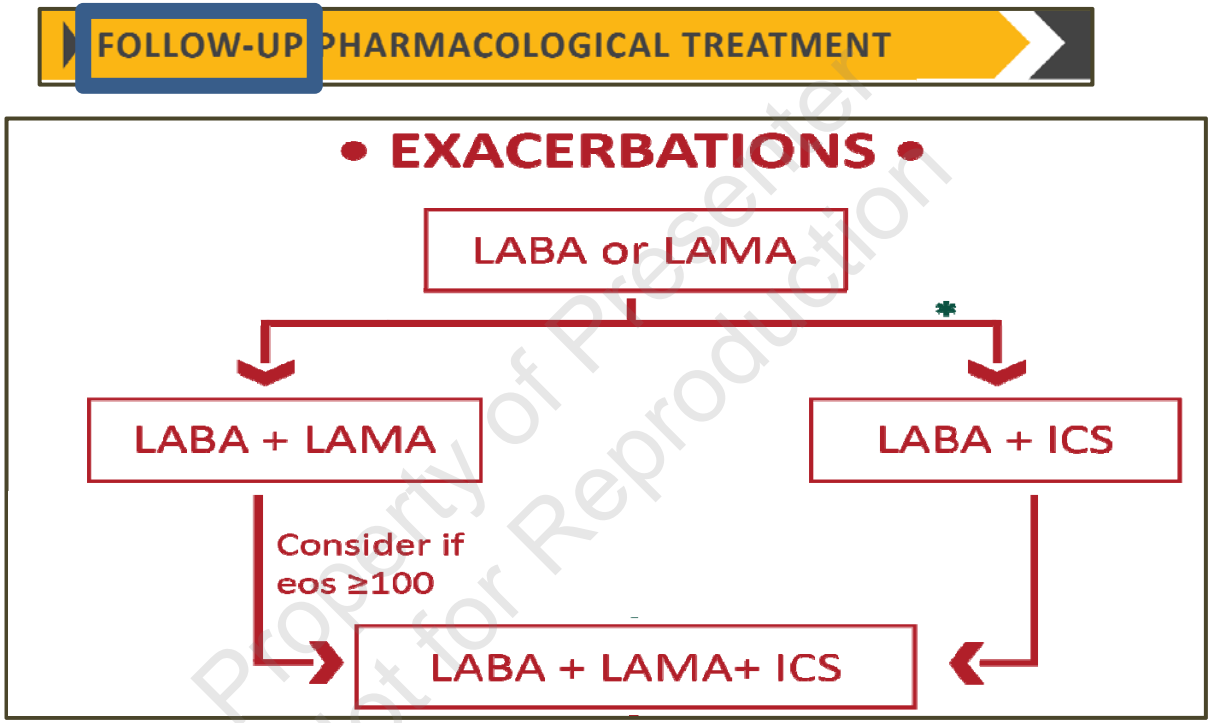
CS=inhaled corticosteroids; LABA=Long acting beta agonists; LAMA=Long acting anti-muscarinic

Take Home Points

ICS=Inhaled corticosteroids

LABA=Long acting beta agonists

LAMA=Long acting anti-muscarinic



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** Consider if eos ≥ 300 or eos ≥ 100 AND ≥2 moderate exacerbations / 1 hospitalization*

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CASE # 2 65 year old woman

Symptoms

- Stable dyspnea.
- No cough or sputum production. No wheezing. No chest tightness.
- History of LLL pneumonia 3 months prior. No other exacerbations for the past 2 years.

Medications

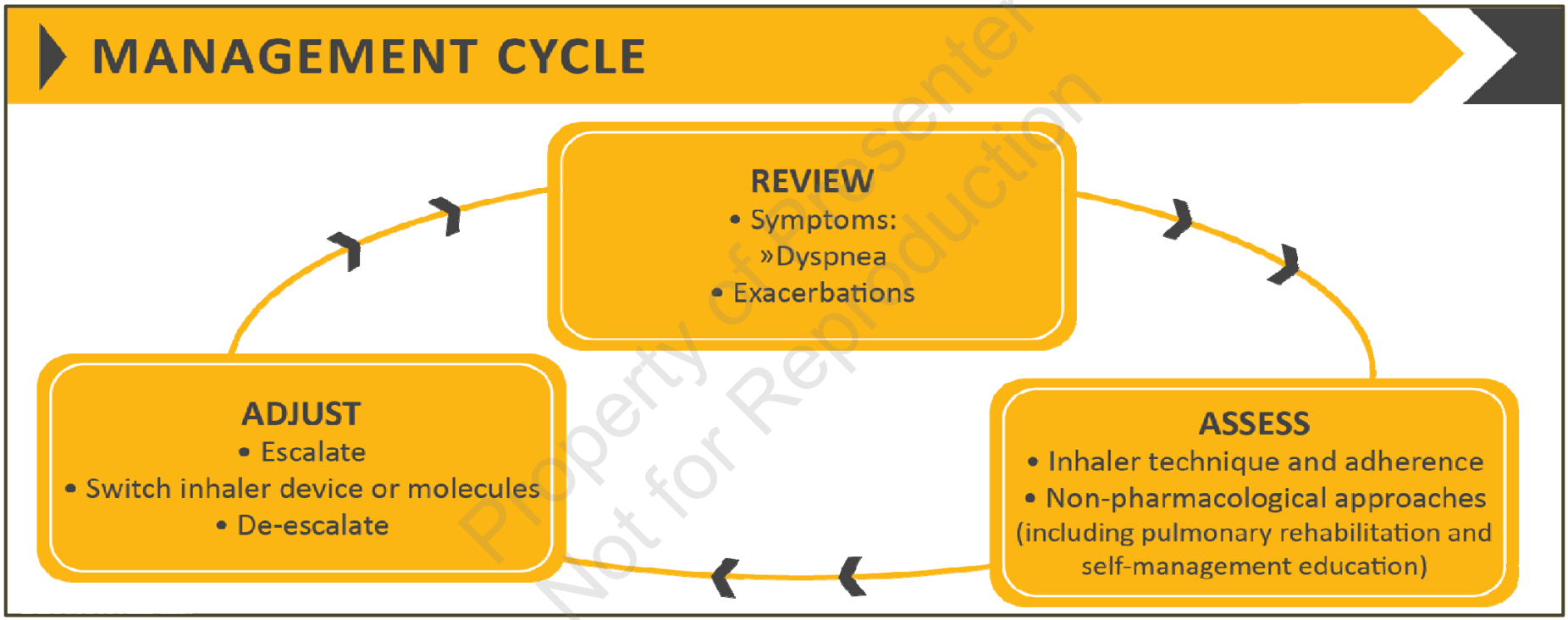
- Fluticasone furoate, vilanterol, tiotropium (ICS/LABA/LAMA)

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ICS=Inhaled corticosteroids LABA=Long acting beta agonists LAMA=Long acting anti-muscarinic

What would you do with her medications?

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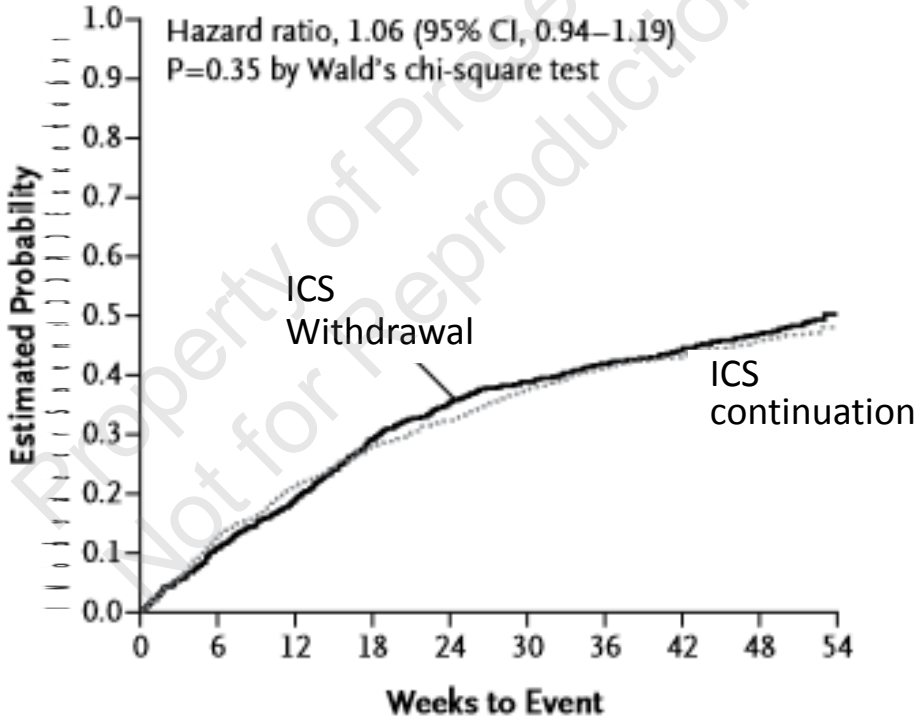
Withdrawal of inhaled glucocorticoids and exacerbations of COPD (WISDOM)

- Design
  - Six week run in : fluticasone propionate, tiotropium, salmeterol
  - Continuation Group : No change
  - Withdrawal Group : Steroid withdrawal over 18 weeks

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Magnussen. N Engl J Med 2014; 371

Withdrawal of Inhaled Glucocorticoids and Exacerbations of COPD (WISDOM)



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ICS=Inhaled corticosteroids

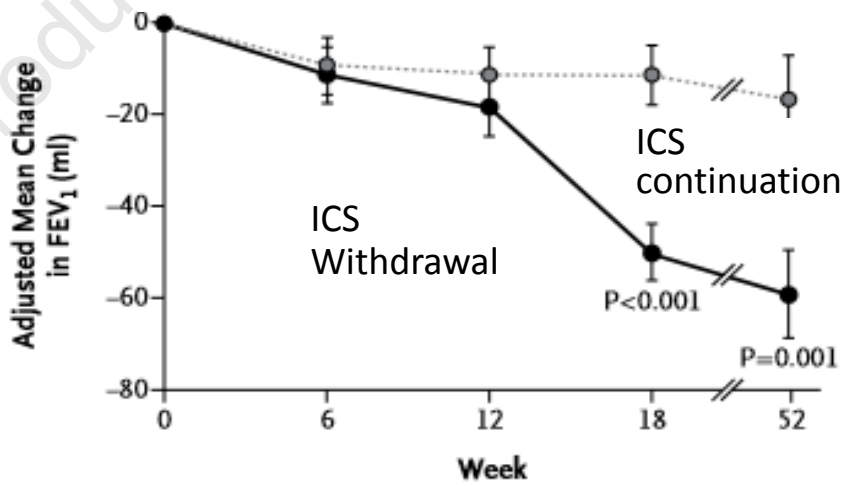
Magnussen. N Engl J Med 2014; 371 : 14

Withdrawal of inhaled glucocorticoids and exacerbations of COPD (WISDOM)

- Discontinuation of steroids is not an inferior strategy

- What is the harm in using inhaled corticosteroids?

FEV1 was slightly lower



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ICS=Inhaled corticosteroids

Magnussen. N Engl J Med 2014; 371 : 14

ICS– Pneumonia risk

Study	Steroid	Risk
TORCH	Fluticasone	19.6 vs 12.3% (p<0.001)
Ernst	Multiple	RR 1.7 (95% CI 1.63 – 1.77)
INSPIRE	Fluticasone	HR 1.94 (95% CI 1.19 – 3.17)
Sin	Budesonide	HR 1.05 (95% CI 0.81 – 1.37)
Kew	Fluticasone	OR 1.78 (95% CI 1.50 – 2.21)
Kew	Budesonide	OR 1.62 (95% CI 1.00 – 2.62)
Drummond	Multiple	RR 1.34 (95% CI 1.03 – 1.75)
IMPACT	Fluticasone	HR 1.53 (95% CI 1.22 – 1.92)

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ICS=Inhaled corticosteroids

Lipson. N Engl J Med 2018; 378 : 18
Ernst. Eur Resp J 2015; 45 : 525

Other Potential ICS Concerns

- Osteoporosis and Bone Fracture
- Mycobacterial Infection: Tuberculosis and Non Tuberculous
- Diabetes Mellitus
- Adrenal Suppression
- Myopathy
- Dysphonia
- Cataracts and Glaucoma

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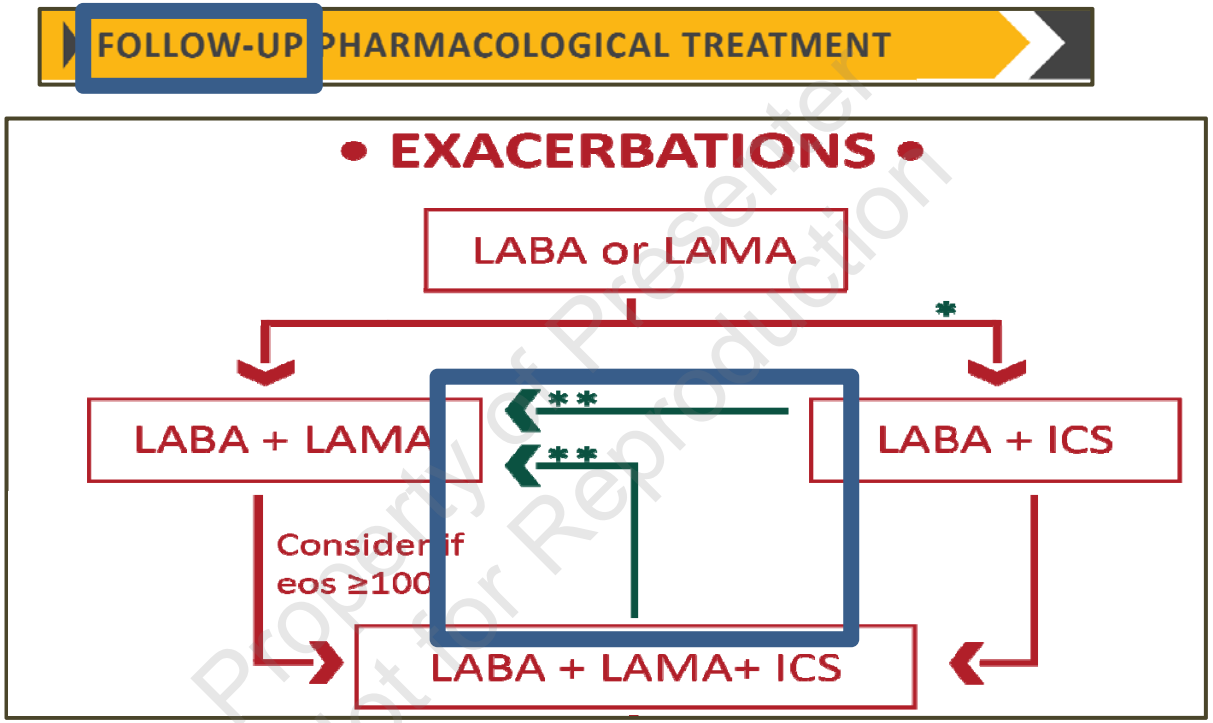
ICS=Inhaled corticosteroids

Take Home Points

ICS=Inhaled corticosteroids

LABA=Long acting beta agonists

LAMA=Long acting anti-muscarinic



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*** Consider de-escalation of ICS or switch if pneumonia, inappropriate original indication or lack of response to ICS***

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CASE # 3 66 year old woman

Symptoms

- Wheezing and chest tightness
- No cough or sputum production
- Six exacerbations in the last year. All requiring hospitalization.

Other Data

- Quit smoking 5 years ago. 30 pack year history.
- Salmeterol; Fluticasone; Tiotropium (LABA/ICS/LAMA)
- Absolute Eosinophils 90
- Spiro (POST) FEV1 / FVC Ratio 61%; FEV1 60%

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ICS=Inhaled corticosteroids; LABA=Long acting beta agonists; LAMA=Long acting anti-muscarinic

What would you do next? Add:

a) Additional ICS
b) Roflumilast
c) Azithromycin
d) Chronic Prednisone

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ICS=Inhaled corticosteroids

What would you do next? Add:

a) Additional ICS

b) Roflumilast

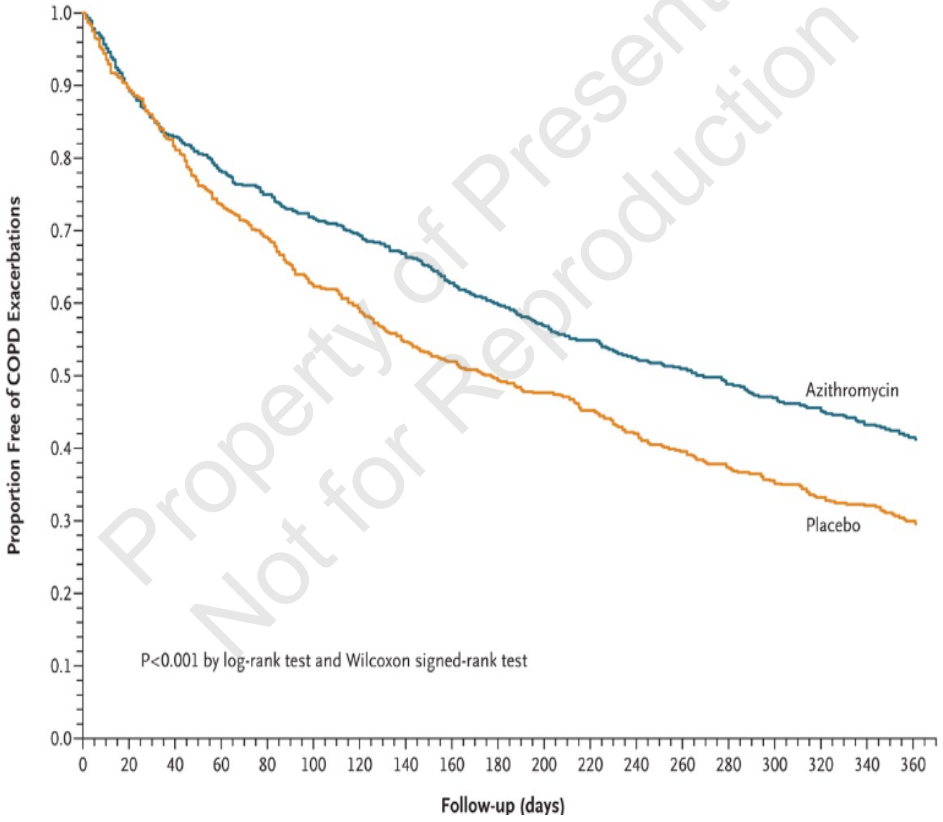
c) Azithromycin

d) Chronic Prednisone

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ICS=Inhaled corticosteroids

Azithromycin for Prevention of COPD Exacerbations



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Albert RK. N Engl J Med 2011; 365 : 689

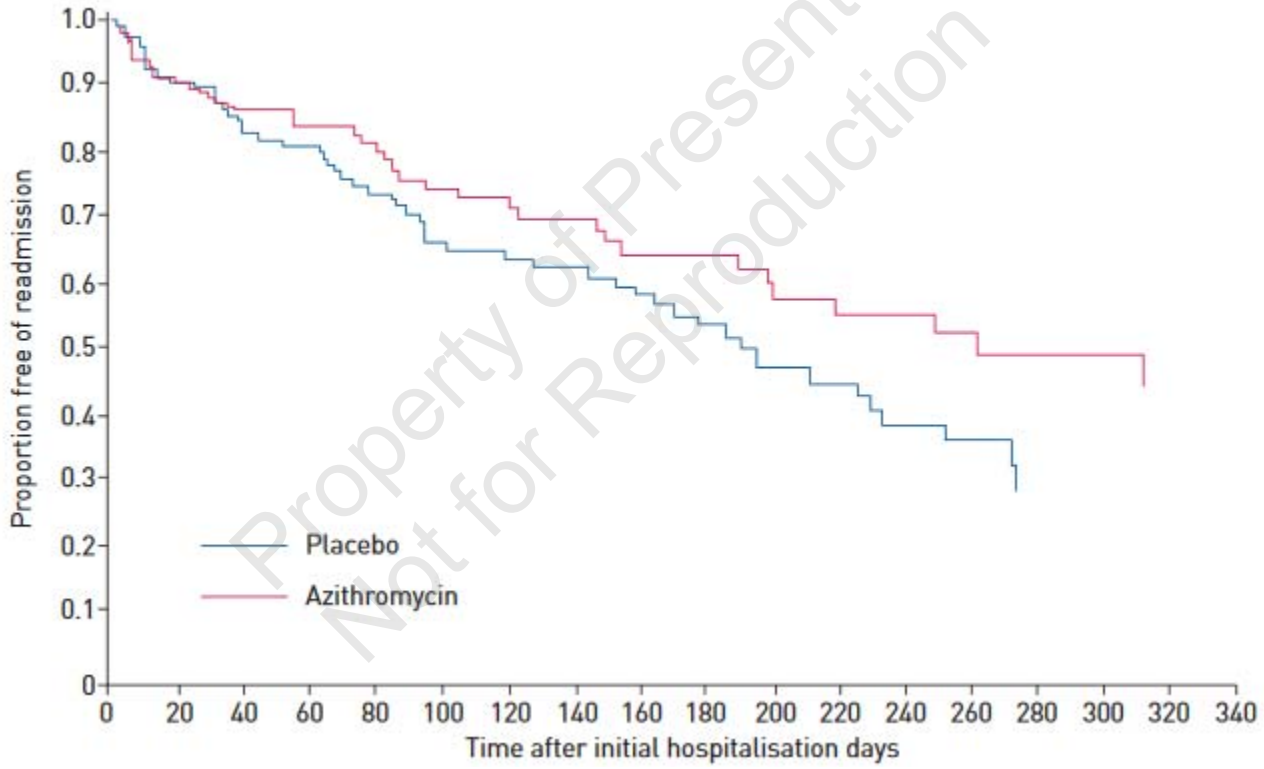
Predictors of Response to Daily Azithromycin Exacerbations

- Azithromycin (250 mg daily) or placebo for 12 months
- Treatment benefit was greatest in
  - Ex-smokers
  - Age >65
  - GOLD Spirometry Stage II, III
- No effect in smokers

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Han, M. AJRCC. 2014 Jun 15;189(12)

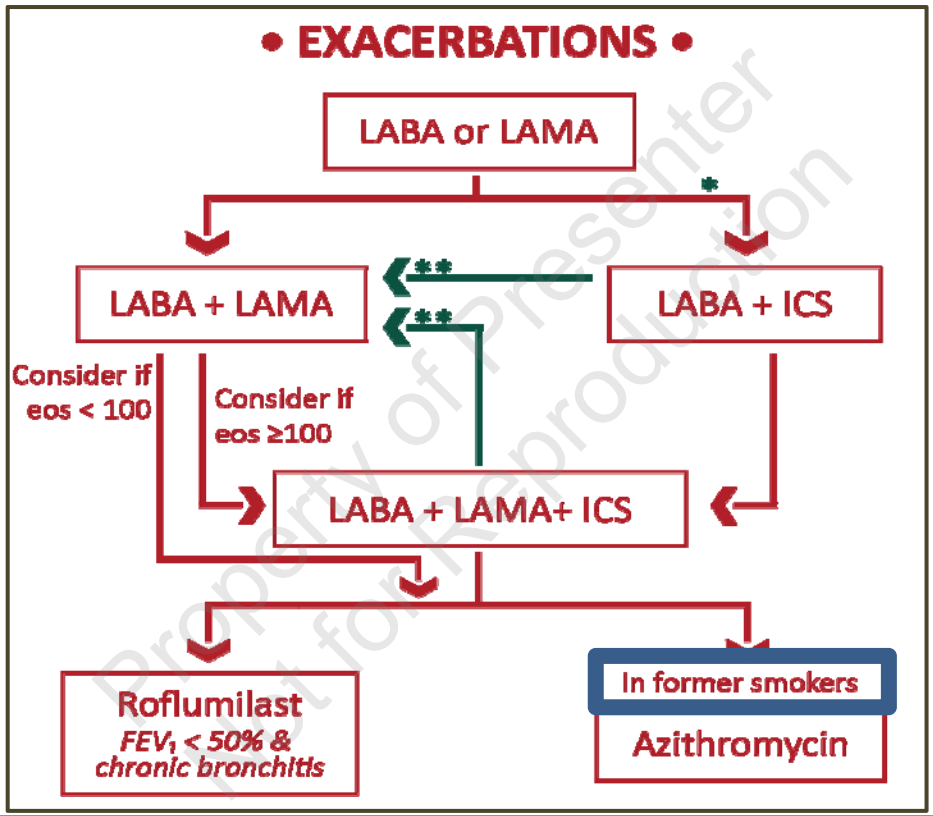
Chronic Azithromycin and Readmissions



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Krishnan JK. Eur Respir J. 2019; 53

Take Home Points



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Consider in:

- **GOLD II, III**
- **Exacerbations requiring hospitalizations**
- **Age >65**

** Consider if eos ≥ 300 or eos ≥ 100 AND ≥2 moderate exacerbations / 1 hospitalization*
*** Consider de-escalation of ICS or switch if pneumonia, inappropriate original indication or lack of response to ICS*

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CASE # 3 66 year old woman

Symptoms

- Wheezing and chest tightness
- No cough or sputum production
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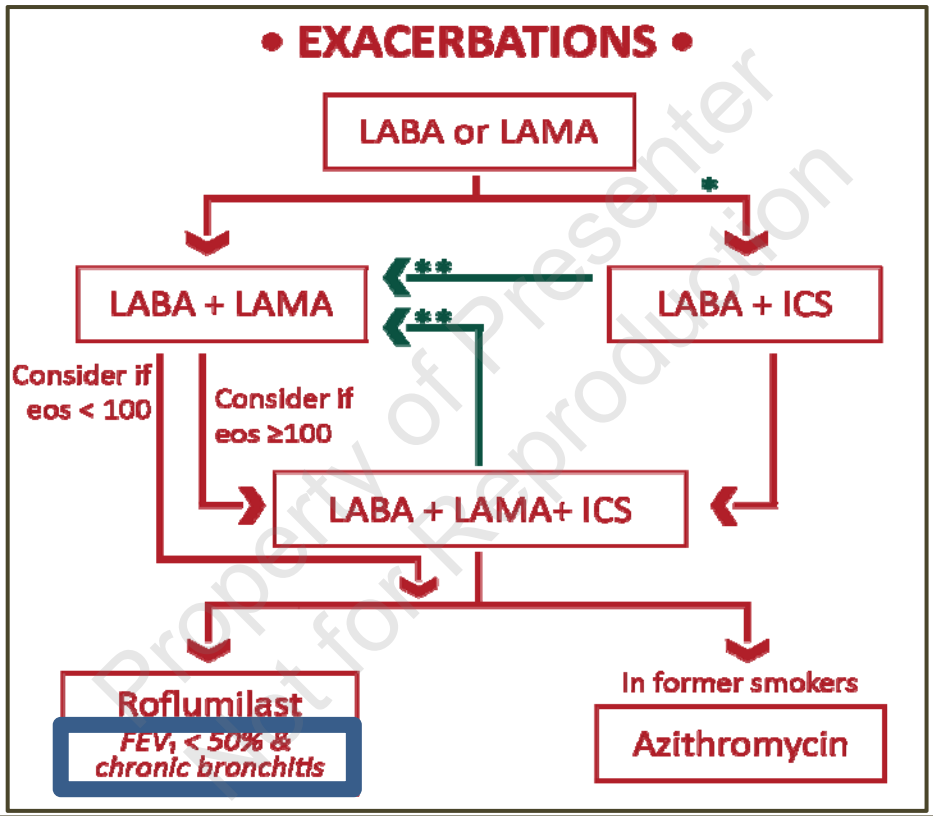
Other Data

- Quit smoking 5 years ago. 30 pack year history.
- Salmeterol; Fluticasone; Tiotropium (LABA/ICS/LAMA)
- Absolute Eosinophils 90
- Spiro (POST) FEV1 / FVC Ratio 61%; FEV1 60%

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ICS=Inhaled corticosteroids; LABA=Long acting beta agonists; LAMA=Long acting anti-muscarinic

Take Home Points



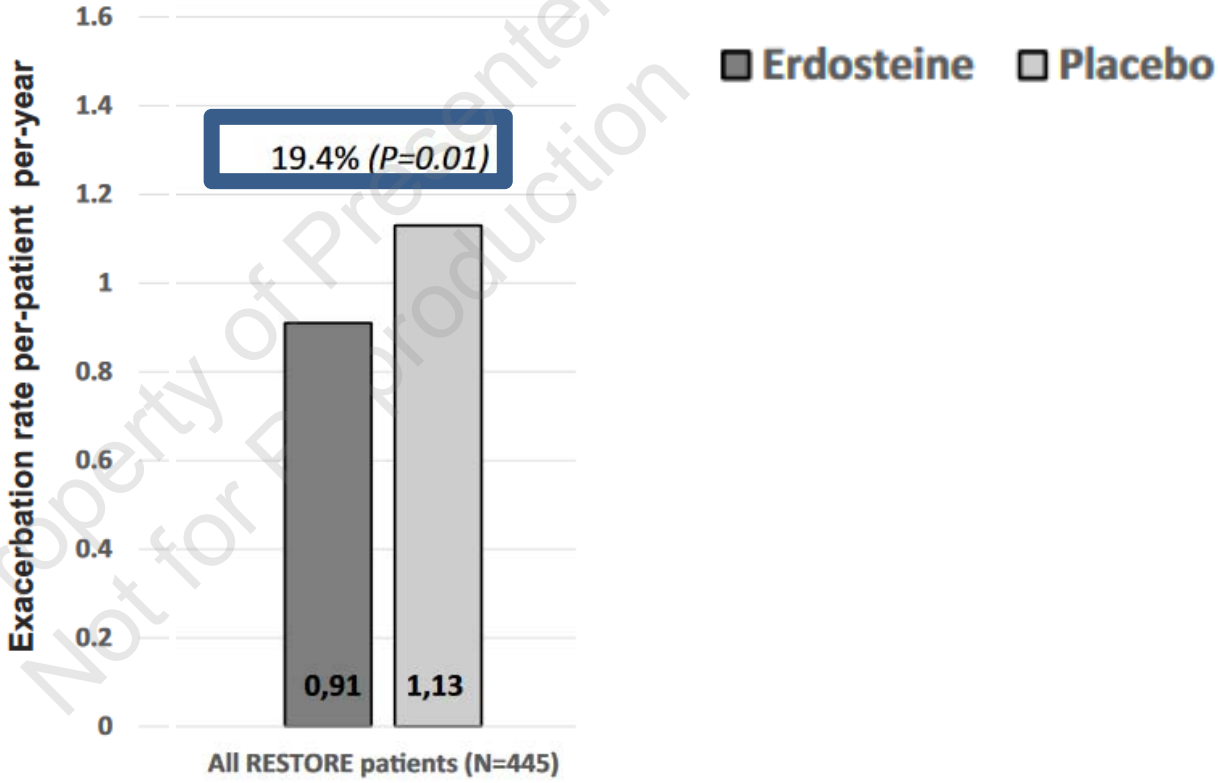
Avoid in:
-low BMI risk of diarrhea

** Consider if eos ≥ 300 or eos ≥ 100 AND ≥2 moderate exacerbations / 1 hospitalization*
*** Consider de-escalation of ICS or switch if pneumonia, inappropriate original indication or lack of response to ICS*

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Other Medications for Exacerbations

RESTORE Study



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Calverley, P. Int J of COPD 2019:14

What's on the Horizon for Management of COPD Exacerbations?

- Following CRP to guide antibiotic therapy

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Butler, C. NEJM 2019

What's on the Horizon for Management of COPD Exacerbations?

- Following CRP to guide antibiotic therapy
- Erdosteine:
  - an oral mucoactive agent with antioxidant and anti-inflammatory properties

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Butler, C. NEJM 2019
Calverley, P. Int J of COPD 2019:14

What's on the Horizon for Management of COPD Exacerbations?

- Following CRP to guide antibiotic therapy
- Erdosteine
- ?Chitotriosidase activity as a possible a predictor of future exacerbations
- ?PD3/4 inhibitors

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Butler, C. NEJM 2019
Calverley, P. Int J of COPD 2019:14
Harlander, M. Lung 2020 Jan 25

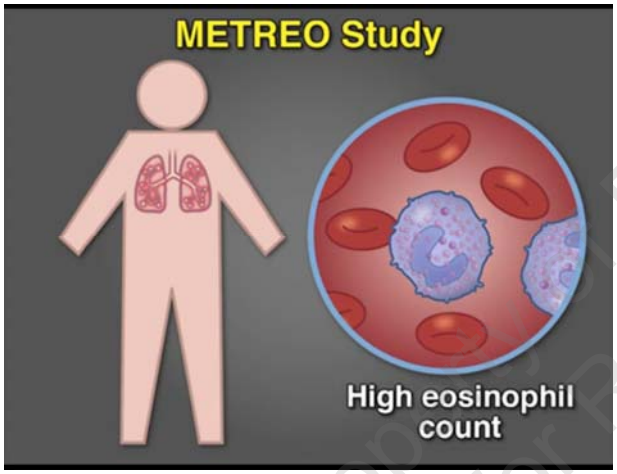
Other Hot Topics in COPD

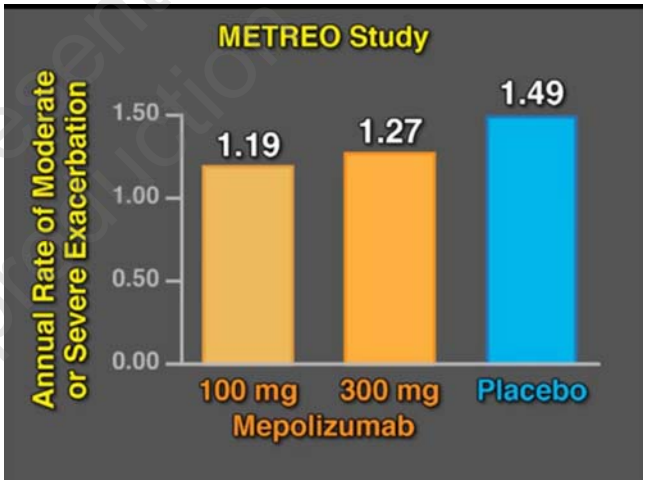
- Biologics
- Lung volume reduction
- Non-Invasive Ventilation
- New nomenclature

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Mepolizumab in Eosinophilic COPD:

Study Design





blood eosinophil count ≥150 at screening or at least 300 during previous year

P=0.07 P=0.14

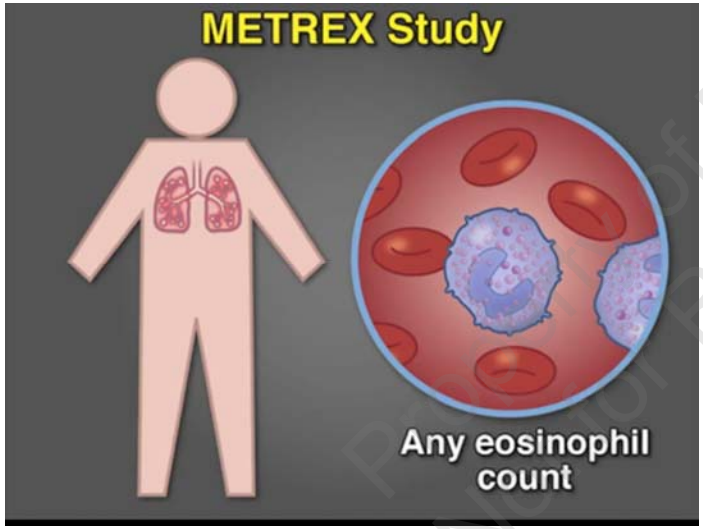
Pavord. N Engl J Med. 2017

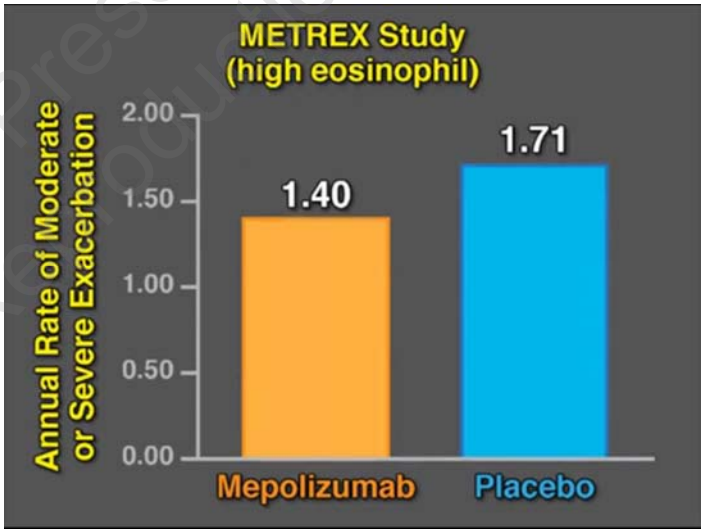
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Mepolizumab in Eosinophilic COPD:

Study Design

Blood eosinophil count ≥150 at screening or at least 300 during previous year



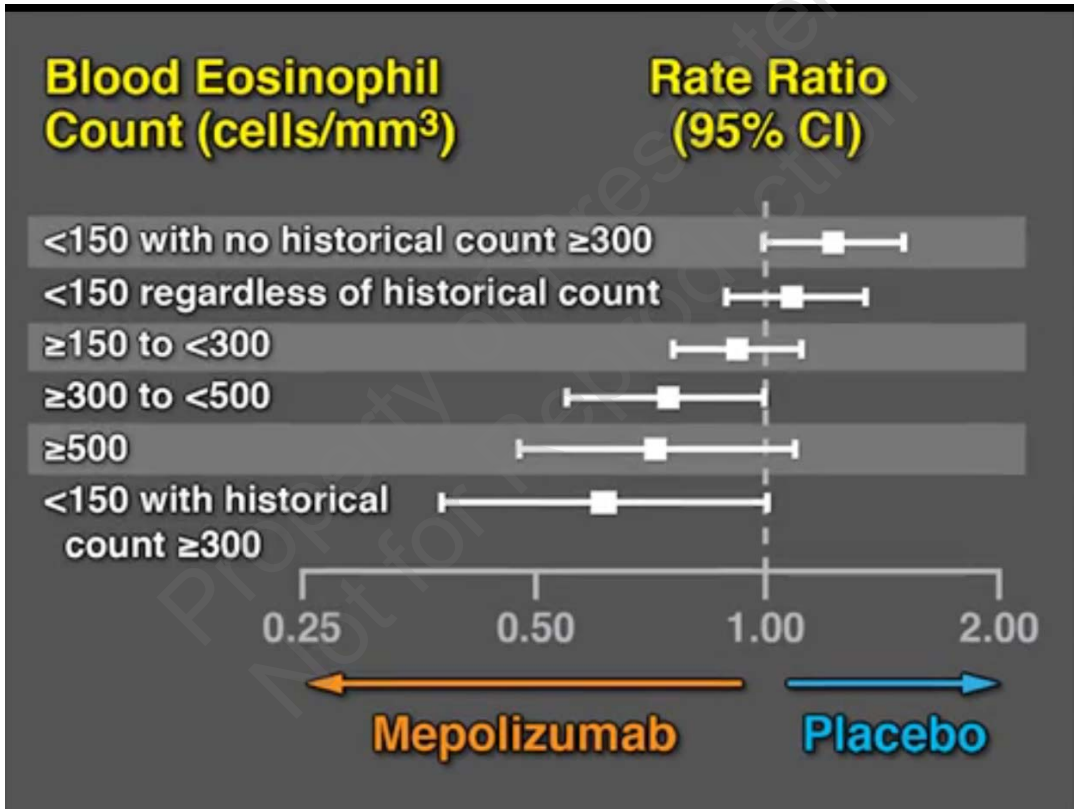


P=0.04

Pavord. N Engl J Med. 2017

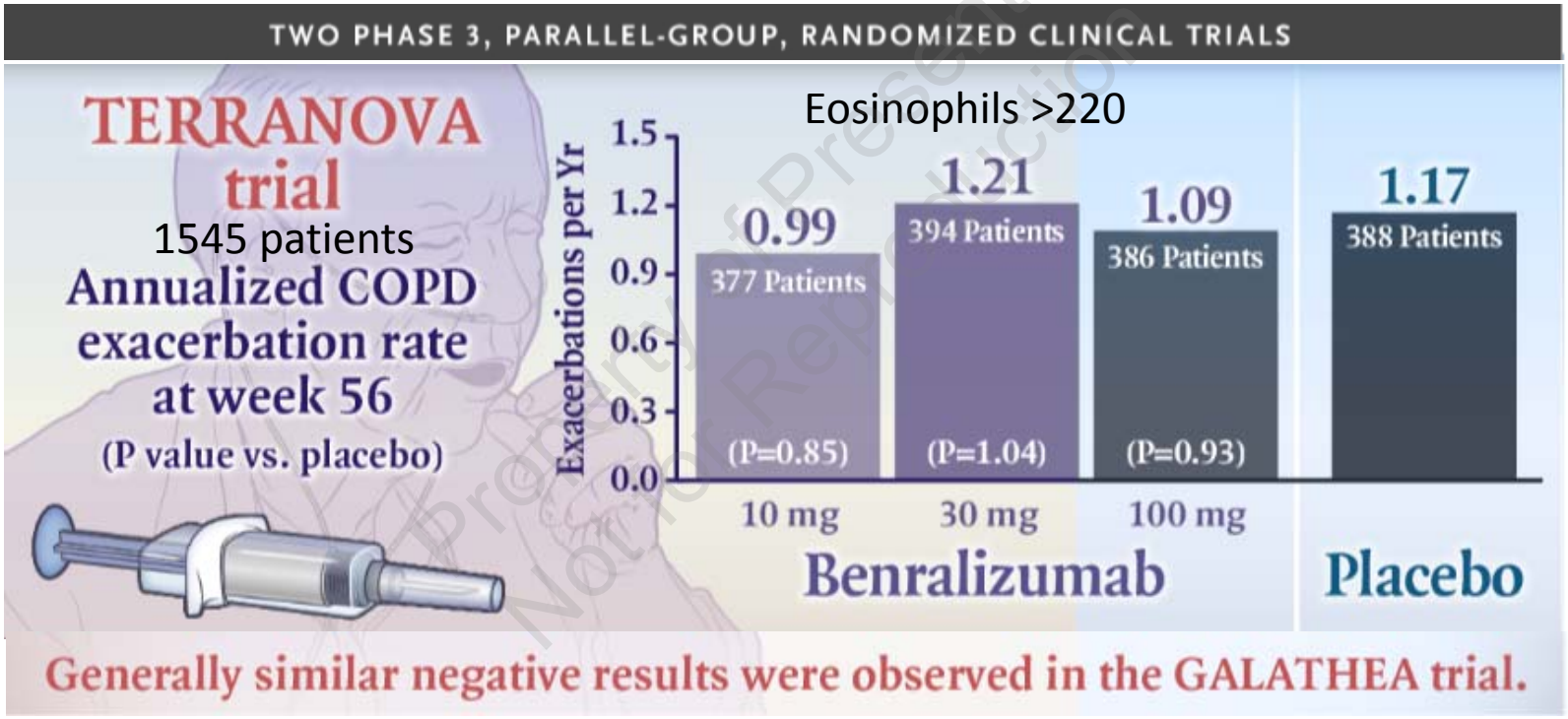
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Mepolizumab in Eosinophilic COPD:



Pavord. N Engl J Med. 2017

Benralizumab to Prevent COPD Exacerbations



1120 patients

Criner G. NEJM. 2019; 381

One of the following is INCORRECT:

A. Lung volume reduction surgery (LVRS) improves survival

B. LVRS improves quality of life

C. LVRS improves dyspnea

D. LVRS should be consider only in high exercise capacity patients

E. LVRS improves exercise tolerance

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One of the following is INCORRECT:

A. Lung volume reduction surgery (LVRS) improves survival

B. LVRS improves quality of life

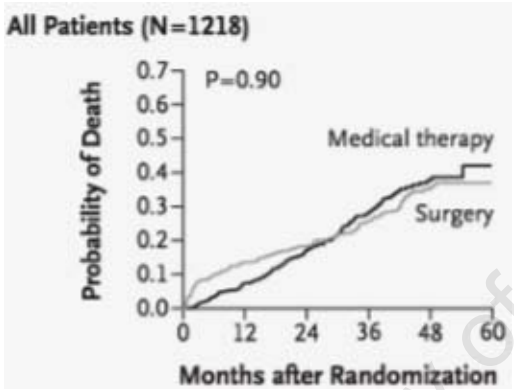
C. LVRS improves dyspnea

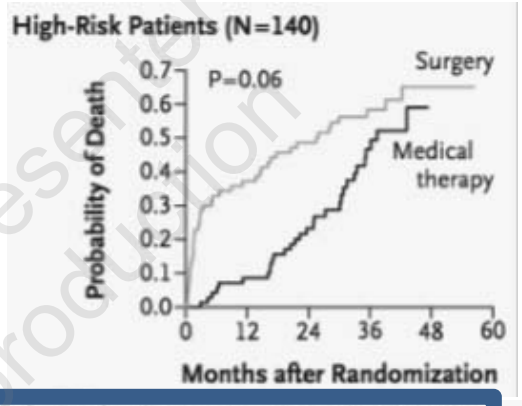
D. LVRS should be consider only in high exercise capacity patients

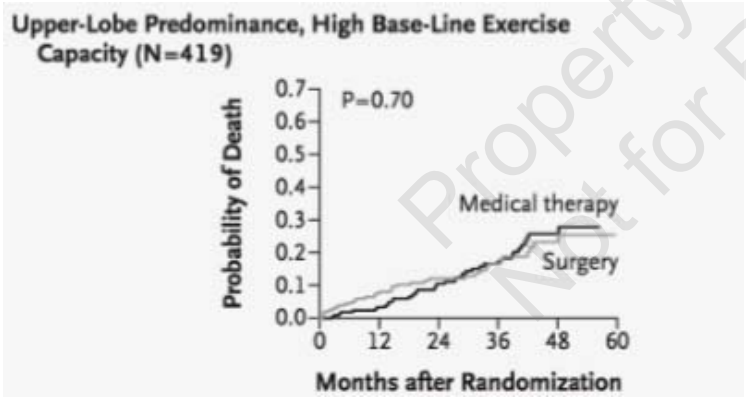
E. LVRS improves exercise tolerance

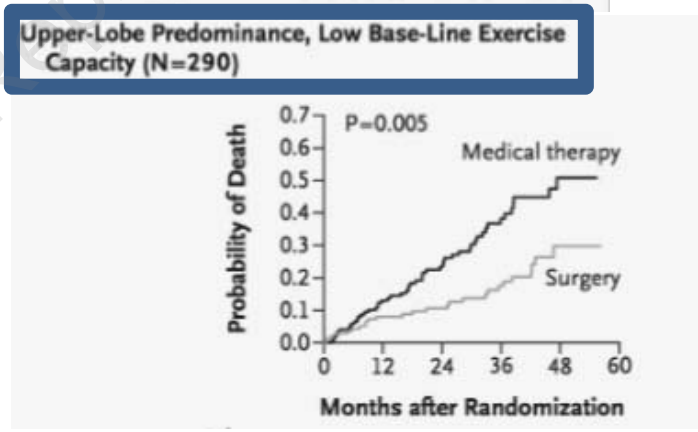
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NETT Trial





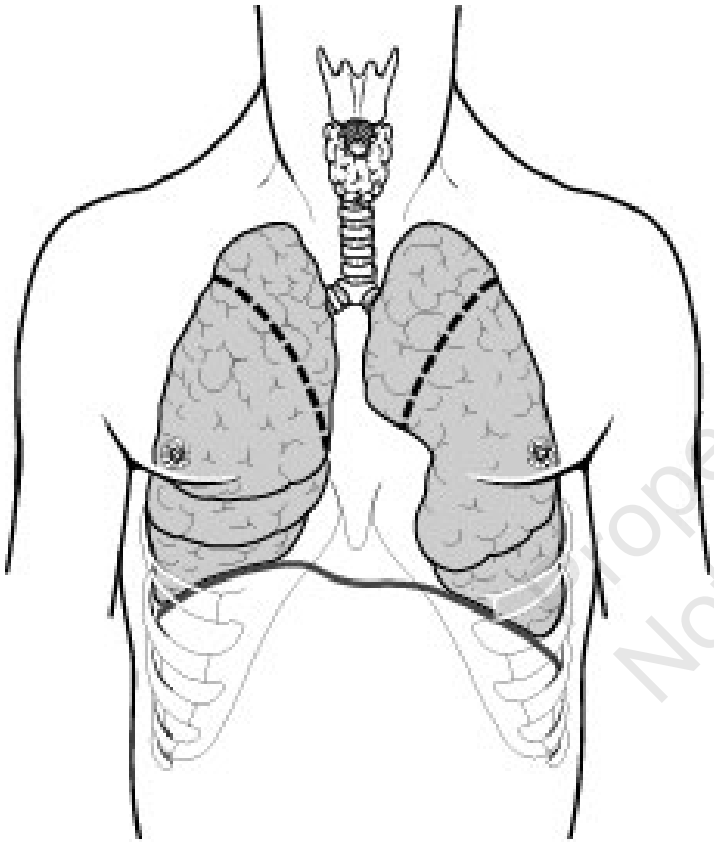


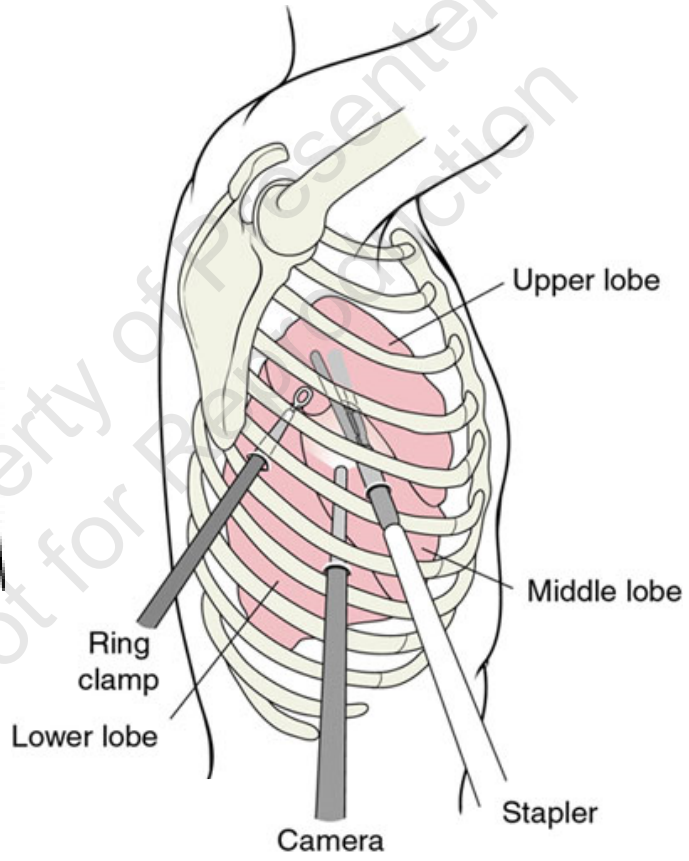


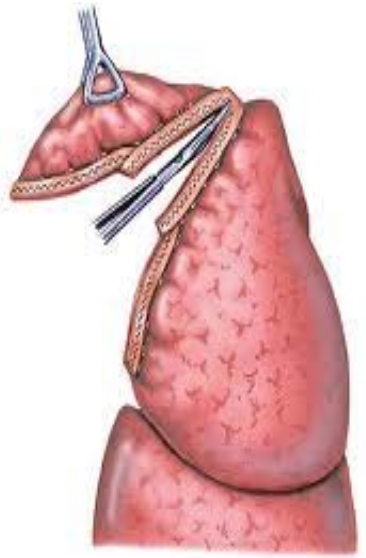
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N Engl J Med. 2003 May 22; 348

Lung Volume Reduction Surgery

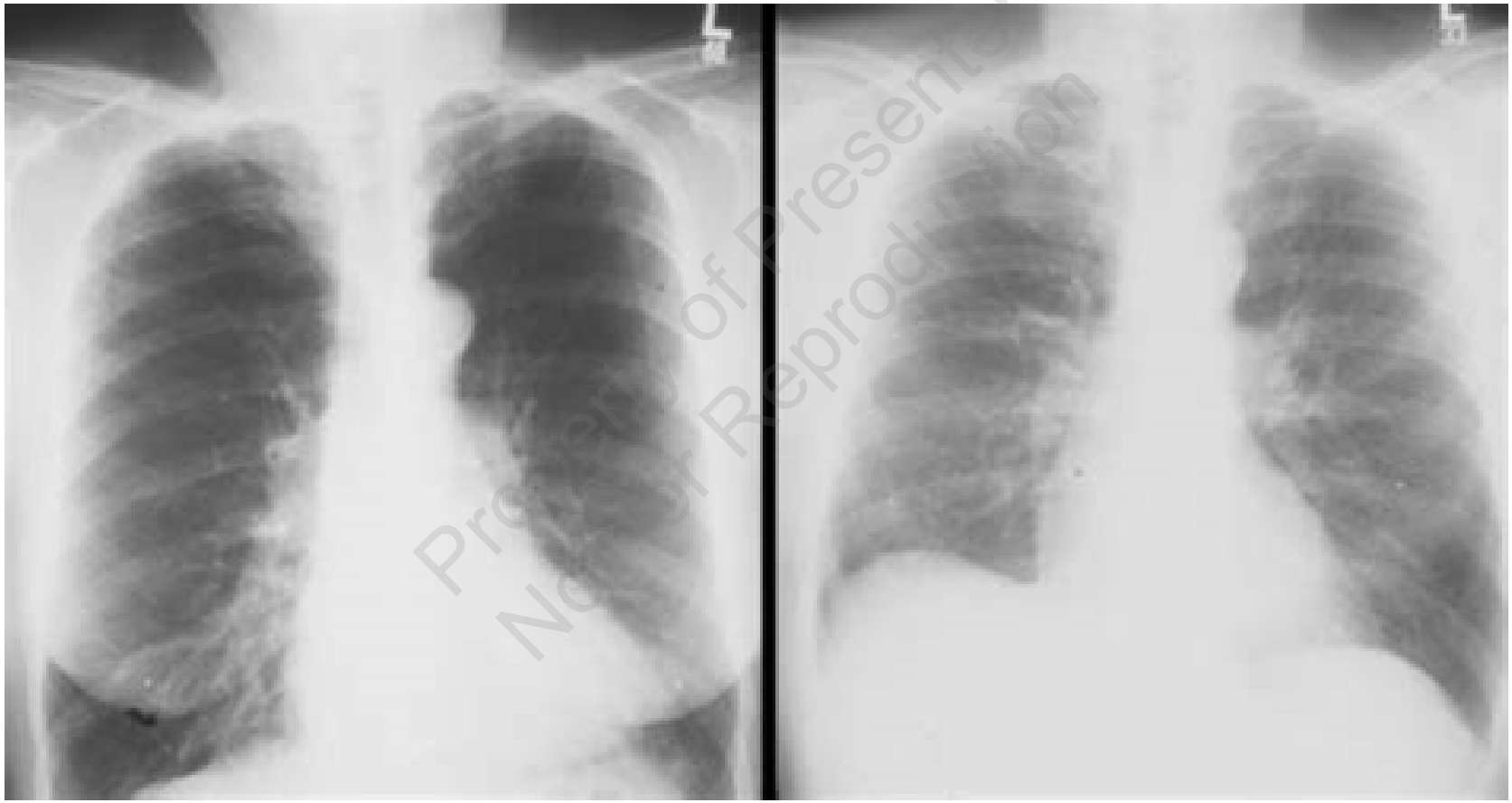






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Lung Volume Reduction Surgery



Bronchoscopic (Endoscopic) Lung Volume Reduction can be considered in patients with:

A. Large bullae

B. Heterogeneous disease and RV ≥175%

D. Recurrent exacerbations

E. DLCO <20%

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RV=residual volume DLCO=diffusion capacity

Bronchoscopic lung volume reduction can be considered in:

A. Patients with large bullae

B. Heterogeneous disease and RV ≥175

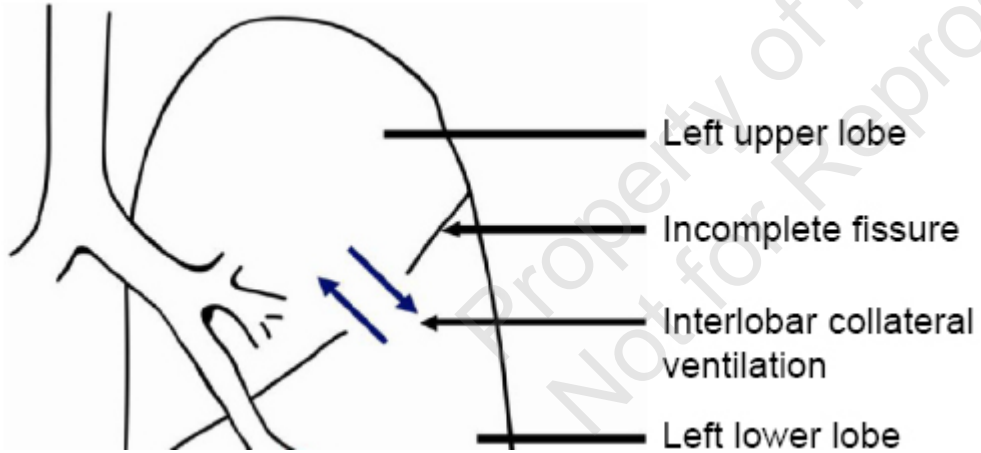
D. Recurrent exacerbations

E. DLCO <20%

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Evaluate by CT

- Intact fissure



- Heterogeneous Emphysema



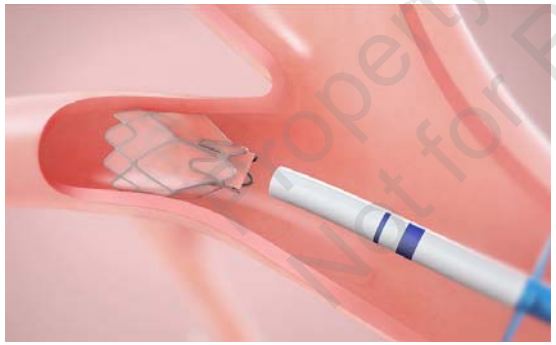
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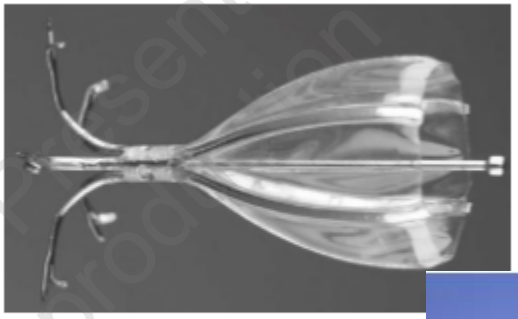
Sciurba FC. NEJM 2010; 36
Koster D. Int J of COPD. 13 April 2016 113

Bronchoscopic (Endoscopic) Lung Volume Reduction



Zephyr





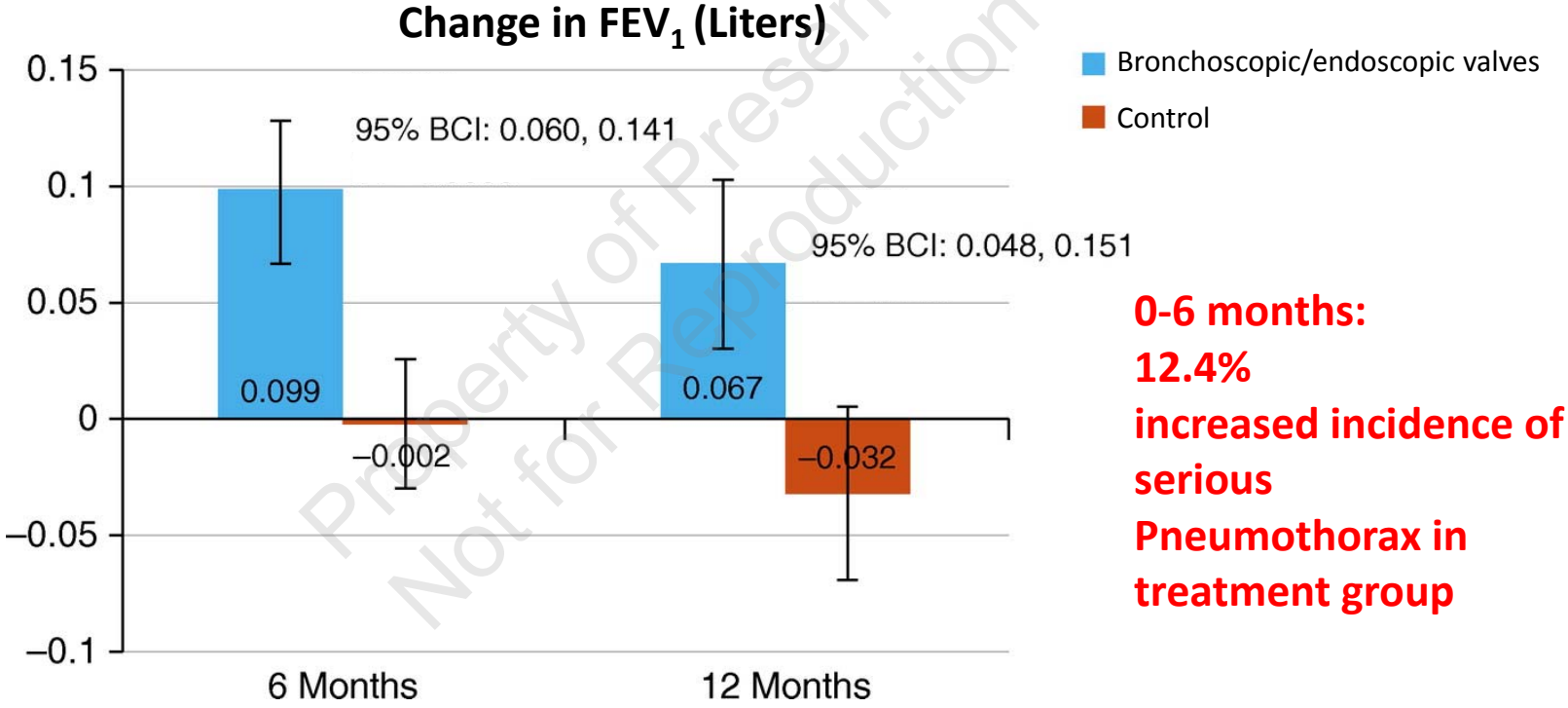
Spiration



Placement of valves does not preclude subsequent LVRS or lung transplant

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EMPROVE: Bronchoscopic (Endoscopic) lung volume reduction Trial

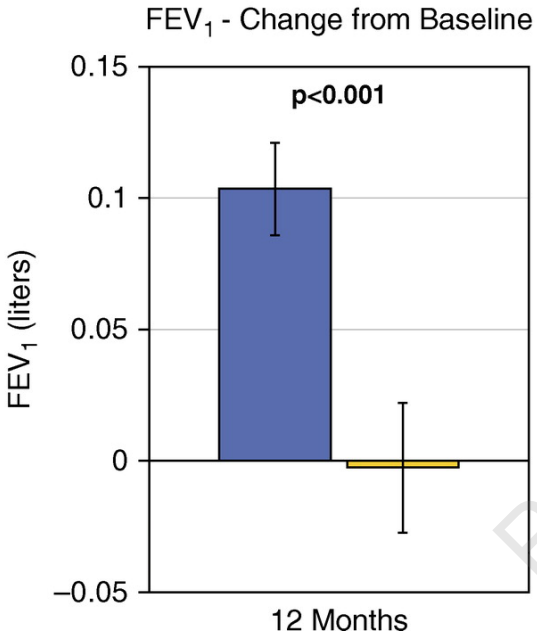


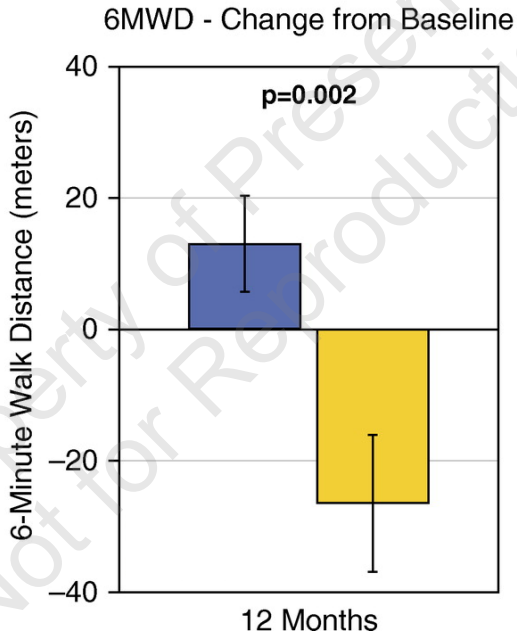
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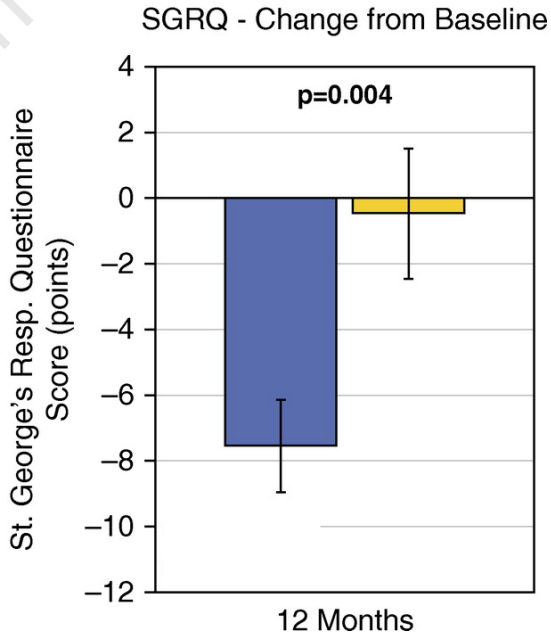
0-6 months:
12.4%
increased incidence of serious Pneumothorax in treatment group

Criner G. AJRCC 2019; 200

LIBERATE: Bronchoscopic (Endoscopic) Lung Volume Reduction Trial







Risk of pneumothorax:
Day 0-45: 27%
Day 45-1 year: 7%

- Bronchoscopic/endoscopic valves
- Control

Criner GJ. AJRCC 2018; 198

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Bronchoscopic (Endoscopic) Lung Volume Reduction

- Valve Placement
  - Valves placed during 30-60 min bronchoscopy
  - 3-5 valves of varying sizes placed in segmental airways of one lobe

- Post – procedure management
  - Admitted 3-5 days to monitor for pneumothorax, exacerbation, infection
  - Regular follow up at 2 weeks, 6 weeks, then 3, 6, 9, 12 months

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Non invasive ventilation in stable COPD should:

A. be considered based on level of hypoxia

B. be considered based on level of hypercarbia $\geq$ 45

C. preferentially use VAPS technology

D. be set to IPAP $\geq$18cmH2O

E. be considered in a patient at the time of discharge from hospitalization due to a severe acute exacerbation

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VAPS=Volume Assured Pressure Support IPAP=inspiratory positive airway pressure

Non invasive ventilation in stable COPD should:

A. be considered based on level of hypoxia

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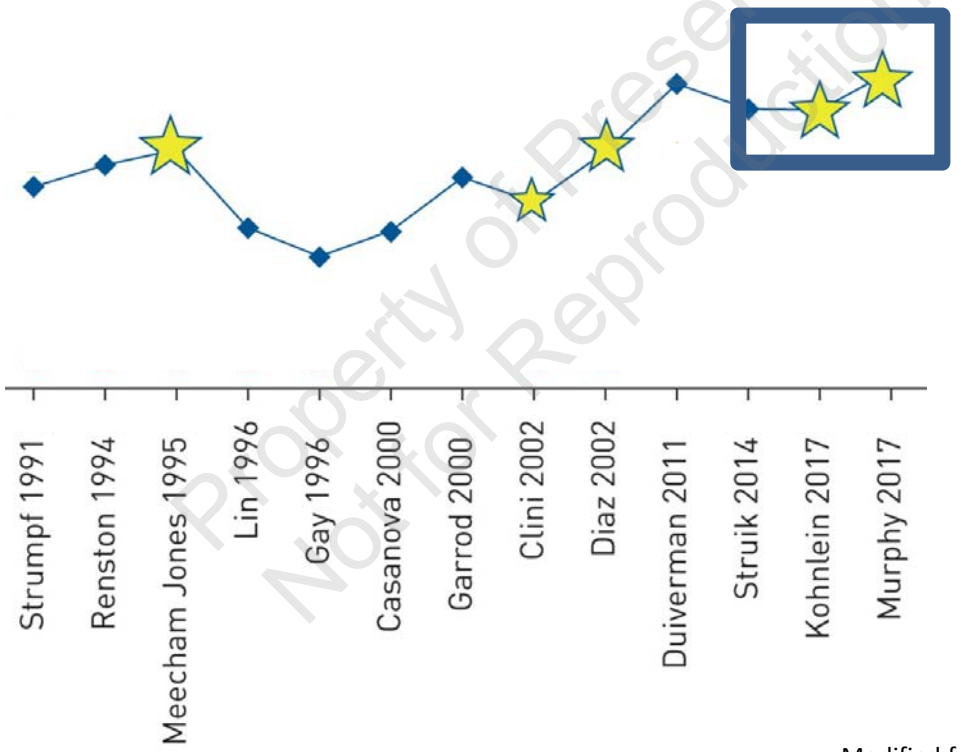
D. be set to IPAP >18cmH2O

E. be considered in a patient at the time of discharge from hospitalization due to a severe acute exacerbation

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VAPS=Volume Assured Pressure Support IPAP=inspiratory positive airway pressure

Trials in Non Invasive Ventilation (NIV) for Hypercapnic COPD



Positive Results

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Modified from Duiverman, ML. ERJ Open Research 4 (2018)

Non Invasive Ventilation (NIV) for Stable Hypercapnic Severe COPD

CLINICAL STATUS	WHO?
STABLE	• **Baseline $PaCO_2$ > 52mmHg** • **Preserved exercise capacity (6MWT >200m)** • **Low annual emergency admission rate**

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Köhnlein T. Lancet Resp Med 2014; 2

Non Invasive Ventilation (NIV) for Stable Hypercapnic Severe COPD

CLINICAL STATUS	WHO?	WHEN?	HOW?	WHY?
STABLE	• **Baseline PaCO2 > 52mmHg** • **Preserved exercise capacity (6MWT >200m)**	• **Stable State** • **Low annual emergency admission rate**	**Targeted CO2 reduction using IPAP ≥ 18 cm H2O**	**Reduces 1 year all cause mortality**

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Köhnlein T. Lancet Resp Med 2014; 2

Non Invasive Ventilation (NIV) for Post Acute Hypercapnic Severe COPD

CLINICAL STATUS	WHO?	WHEN?	HOW?	WHY?
POST ACUTE	• **Following a severe exacerbation of COPD requiring acute NIV**			

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Murphy PB. JAMA 2017; 317

Non Invasive Ventilation (NIV) for Post Acute Hypercapnic Severe COPD

CLINICAL STATUS	WHO?	WHEN?	HOW?	WHY?
POST ACUTE	• **Following a severe exacerbation of COPD requiring acute NIV**	• **2-4 weeks post AECOPD if PaCO2 > 52mmHg**	**Targeted CO2 reduction using IPAP ≥ 18 cm H2O**	**Increases admission-free survival**

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Murphy PB. JAMA 2017; 317

VAPS vs BIPAP in Stable Hypercarbic COPD

No long term studies. No data on survival.

Study	Type of study	Number of patients	Diagnosis	Modes compared
Ambrogio *et al.* [16]	Randomized crossover	28	OHS, COPD, OSA, poliomyelitis,	VAPS vs BPAP
Crisafulli *et al.* [22]	Randomized crossover	9	COPD	VAPS vs. BPAP
Ekkernkamp *et al.* [31]	Prospective study	27	COPD	HI-NPPV vs. VAPS
Ekkernkamp *et al.* [31]	Randomized crossover	14	COPD	VAPS vs. HI-NPPV
Nilius *et al.* [20]	Randomized crossover	14	COPD	VAPS vs. BPAP-ST
Oscroft *et al.* [30]	Randomized controlled	40	COPD	VAPS vs. BPAP
Oscroft *et al.* [29]	Randomized crossover	25	COPD	VAPS vs. BPAP
Kelly *et al.* [25]	Randomized controlled	18	COPD, scoliosis, OHS,	VAPS vs. BPAP-ST

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Modified from Shaughnessy G. Curr Op Pul Med 2019; 25

What's on the Horizon for Management of Stable COPD?

- Nasal high-flow

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Braunlich J. Int J COPD 2019; 14



Chronic Obstructive Pulmonary Diseases:
Journal of the COPD Foundation

Original Research

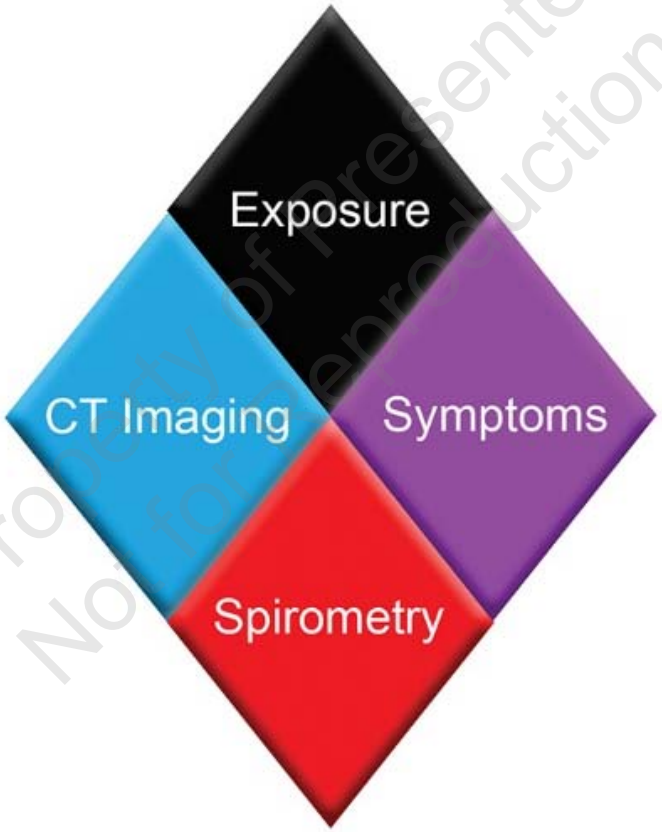
COPDGene® 2019: Redefining the Diagnosis of Chronic Obstructive Pulmonary Disease

Katherine E. Lowe, MSc[1] Elizabeth A. Regan, MD, PhD[2] Antonio Anzueto, MD[3] Erin Austin, PhD[4]

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Special Issue November 2019
Free subscription online
https://journal.copdfoundation.org

COPDGene 2019 Diagnosis



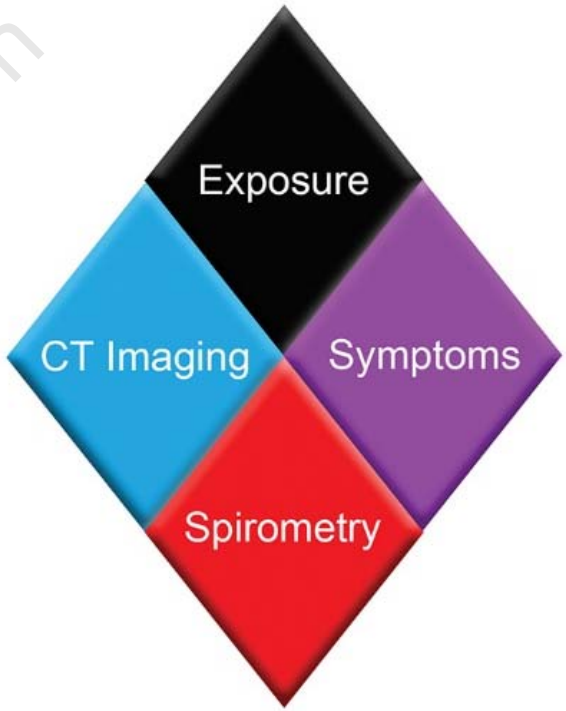
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Lowe K. J COPDF, Nov. 2019

COPDGene 2019 Diagnosis

- **Exposure**:
  - Cigarette smoking ≥ 10 pack-years

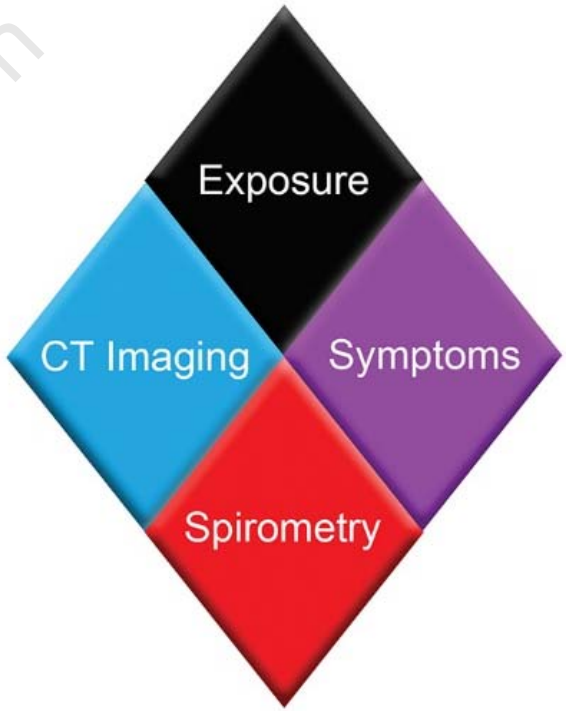
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Lowe K. J COPDF, Nov. 2019

COPDGene 2019 Diagnosis

- **Exposure**:
  - Cigarette smoking ≥ 10 pack-years
- **Symptoms**:
  - mMRC dyspnea ≥ 2 or
  - chronic bronchitis (ATS)

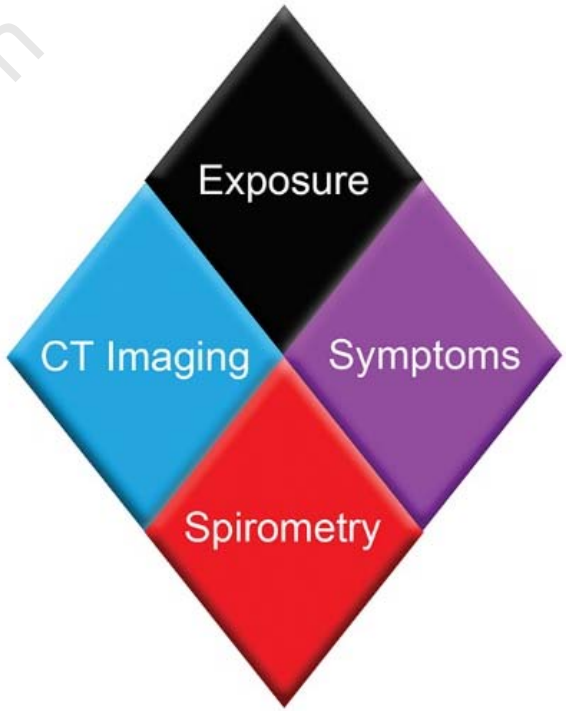


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Lowe K. J COPDF, Nov. 2019

COPDGene 2019 Diagnosis

- **Exposure**:
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- **CT structural disease**:
  - emphysema ≥5%
  - gas trapping ≥15% or airway thickening

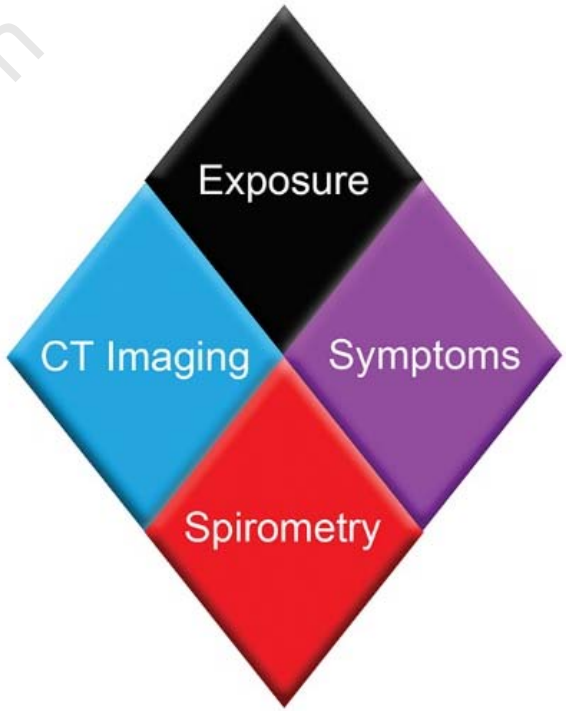


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COPDGene 2019 Diagnosis

- **Exposure**:
  - Cigarette smoking ≥ 10 pack-years
- **Symptoms**:
  - mMRC dyspnea ≥ 2 or
  - chronic bronchitis (ATS)
- **CT structural disease**:
  - emphysema ≥5%
  - gas trapping ≥15% or airway thickening
- **Airflow obstruction**:
  - $FEV_1/FVC < 0.70$ ("classic") or
  - FEV_1 < 80% predicted (PRISm)



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Lowe K. J COPDF, Nov. 2019

Category	Description	Disease Features	
A	Exposure	1	
B	Exposure + CT	**2**	**Possible COPD**
C	Exposure + Symptoms	**2**	
D	Exposure + Spirometry	**2**	
E	Exposure + Symptoms + CT	**3**	**Probable COPD**
F	Exposure + Spirometry + Symptoms	**3**	
G	Exposure + Spirometry + CT	**3**	
H	Exposure + Spirometry + Symptoms + CT	**4**	**Definite COPD**

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Lowe KE et al. Redefining the diagnosis of COPD. J COPDF, submitted 2019

Take Home Points

- The cost of COPD is ballooning

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Take Home Points

- The cost of COPD is ballooning
- Reassess therapies with each visit

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Take Home Points

- The cost of COPD is ballooning
- Reassess therapies with each visit
- Consider better phenotyping your patients
  - Eosinophilia (ICS)
  - Pneumonia (avoid ICS)
  - Recurrent exacerbations (if maximized on inhalers consider roflumilast for chronic bronchitis or azithromycin for former smokers, age>65, hospitalized patient)
  - Early stage (tiotropium)
  - Smokers (ICS and azithromycin less effective)

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Take Home Points

- The cost of COPD is ballooning
- Reassess therapies with each visit
- Consider better phenotyping your patients
- Consider biologics in those with overlapping asthma

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Take Home Points

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- Consider LVRS in patient with upper lobe disease improves survival

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Take Home Points

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- Consider BLVR in patients though significant risk of pneumothorax

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Take Home Points

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- Consider NIV if PCO_2 >52 in stable or post-acute COPD

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Take Home Points

- The cost of COPD is ballooning
- Reassess therapies with each visit
- Consider better phenotyping your patients
- Consider biologics in those with overlapping asthma
- Consider LVRS in patient with upper lobe disease improves survival
- Consider BLVR in patients though significant risk of pneumothorax
- Consider NIV if PCO_2 >52 in stable or post-acute COPD
- COPDGene may be changing the COPD nomenclature

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THANK YOU

Questions?

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