

Gold 2019

Μαρκάτος Μιλτιάδης
Πνευμονολόγος



ΕΝΩΣΗ ΠΝΕΥΜΟΝΟΛΟΓΩΝ ΕΛΛΑΔΑΣ

ΕΤΗΣΙΟ ΣΥΝΕΔΡΙΟ



30 Μαΐου - 2 Ιουνίου 2019

Αθήνα, Ξενοδοχείο Royal Olympic

Δήλωση συμφερόντων

Έχω λάβει τιμητικές αμοιβές για τη παροχή συμβουλευτικών υπηρεσιών, συγγραφή ενημερωτικών εκδόσεων, παρουσίαση επιστημονικού υλικού, από τις εξής φαρμακευτικές εταιρείες τα τελευταία 2 έτη:

AstraZeneca, Chiesi, ELPEN, GSK, Menarini, Novartis, Pharmaten.



GOLD 2019 Report: Chapters

Global Initiative for Chronic Obstructive Lung Disease



GLOBAL STRATEGY FOR THE DIAGNOSIS,
MANAGEMENT, AND PREVENTION OF
CHRONIC OBSTRUCTIVE PULMONARY DISEASE
2019 REPORT

1. Definition and Overview
2. Diagnosis and Initial Assessment
3. Evidence Supporting Prevention & Maintenance Therapy
4. Management of Stable COPD
5. Management of Exacerbations
6. COPD and Comorbidities



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**Global Initiative for Chronic
Obstructive
Lung
Disease**



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COPD Definition

- ▶ Chronic Obstructive Pulmonary Disease (COPD) is a **common**, **preventable** and **treatable** disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases.

Etiology, pathobiology & pathology of COPD leading to airflow limitation & clinical manifestations

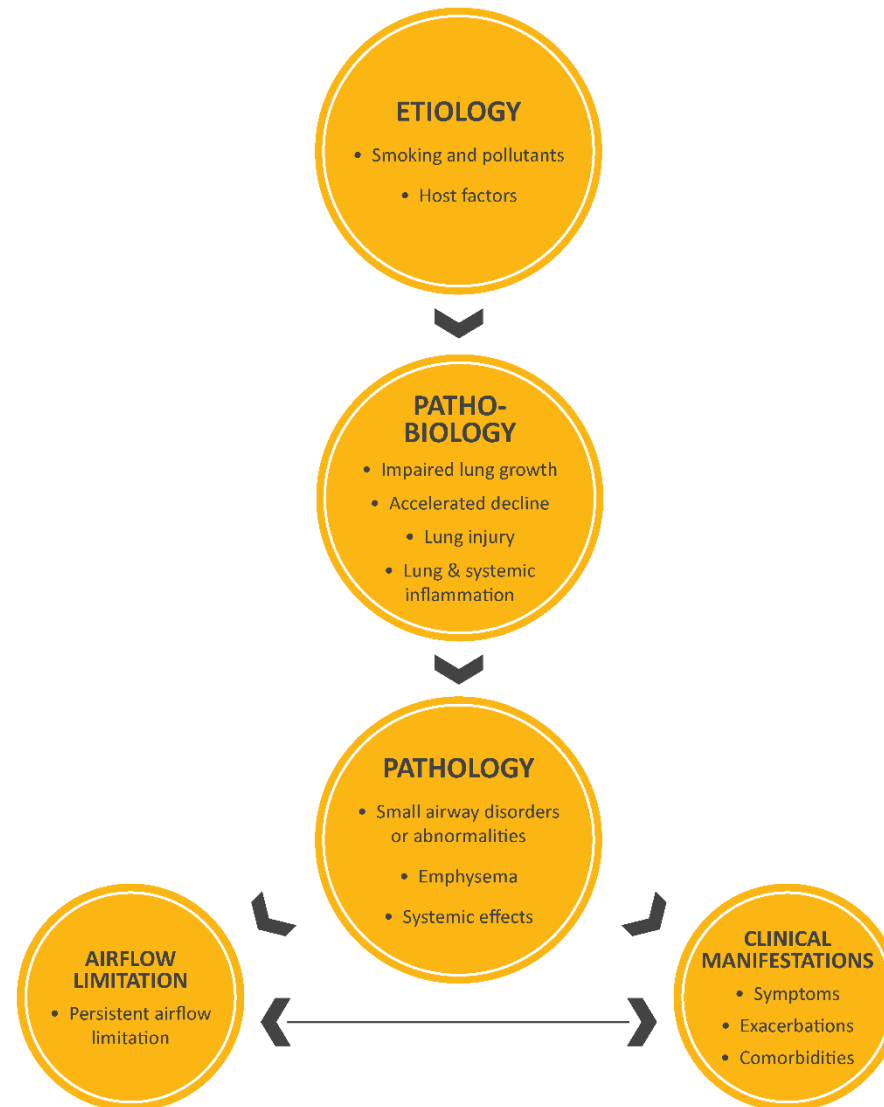


FIGURE 1.1



FEV₁ progression over time

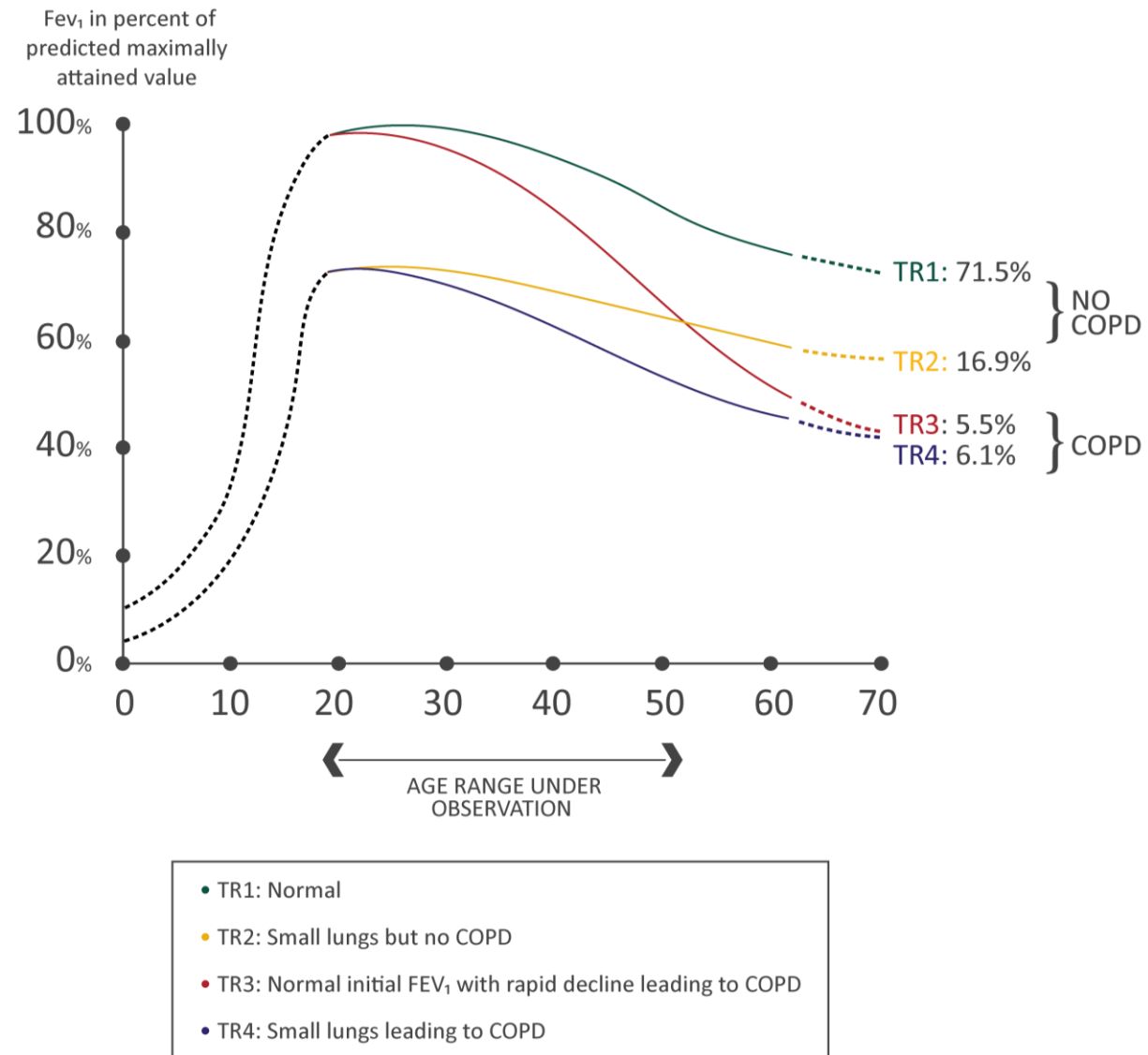


FIGURE 1.2



Prevalence

- ▶ Estimated 384 million COPD cases in 2010.
- ▶ Estimated global prevalence of 11.7% (95% CI 8.4%–15.0%).
- ▶ Three million deaths annually.
- ▶ With increasing prevalence of smoking in developing countries, and aging populations in high-income countries, the prevalence of COPD is expected to rise over the next 30 years.
- ▶ By 2030 predicted 4.5 million COPD related deaths annually.



Factors that influence disease progression

- ▶ Genetic factors
- ▶ Age and gender
- ▶ Lung growth and development
- ▶ Exposure to particles
- ▶ Socioeconomic status
- ▶ Asthma & airway hyper-reactivity
- ▶ Chronic bronchitis
- ▶ Infections



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Diagnosis and Initial Assessment

OVERALL KEY POINTS:

- ▶ COPD should be considered in any patient who has dyspnea, chronic cough or sputum production, and/or a history of exposure to risk factors for the disease.
- ▶ Spirometry is required to make the diagnosis; the presence of a post-bronchodilator $FEV_1/FVC < 0.70$ confirms the presence of persistent airflow limitation.
- ▶ The goals of COPD assessment are to determine the level of airflow limitation, the impact of disease on the patient's health status, and the risk of future events (such as exacerbations, hospital admissions, or death), in order to guide therapy.

Diagnosis and Initial Assessment

▶ PATHWAYS TO THE DIAGNOSIS OF COPD

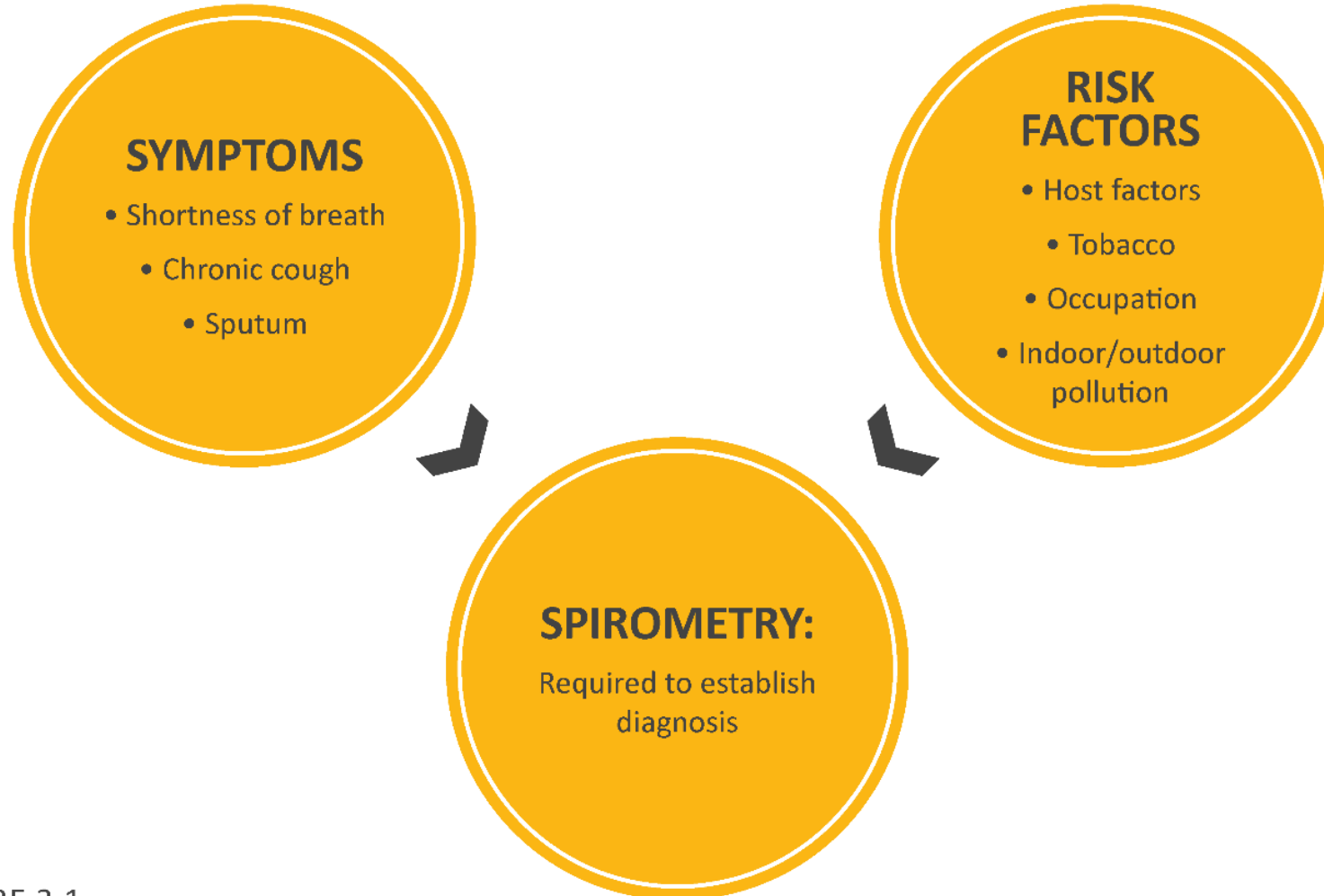


FIGURE 2.1



Post-bronchodilator FEV₁

▶ CLASSIFICATION OF AIRFLOW LIMITATION SEVERITY IN COPD (BASED ON POST-BRONCHODILATOR FEV₁)

In patients with FEV₁/FVC < 0.70:

GOLD 1:	Mild	FEV ₁ ≥ 80% predicted
GOLD 2:	Moderate	50% ≤ FEV ₁ < 80% predicted
GOLD 3:	Severe	30% ≤ FEV ₁ < 50% predicted
GOLD 4:	Very Severe	FEV ₁ < 30% predicted

TABLE 2.4



Choice of thresholds

- ▶ COPD Assessment Test (CAT™)
- ▶ Chronic Respiratory Questionnaire (CCQ®)
- ▶ St George's Respiratory Questionnaire (SGRQ)
- ▶ Chronic Respiratory Questionnaire (CRQ)
- ▶ Modified Medical Research Council (mMRC) questionnaire



COPD Assessment Test (CAT™)

CAT™ ASSESSMENT

For each item below, place a mark (x) in the box that best describes you currently.
Be sure to only select one response for each question.

EXAMPLE: I am very happy	0	X	2	3	4	5	I am very sad	SCORE
I never cough	0	1	2	3	4	5	I cough all the time	
I have no phlegm (mucus) in my chest at all	0	1	2	3	4	5	My chest is completely full of phlegm (mucus)	
My chest does not feel tight at all	0	1	2	3	4	5	My chest feels very tight	
When I walk up a hill or one flight of stairs I am not breathless	0	1	2	3	4	5	When I walk up a hill or one flight of stairs I am very breathless	
I am not limited doing any activities at home	0	1	2	3	4	5	I am very limited doing activities at home	
I am confident leaving my home despite my lung condition	0	1	2	3	4	5	I am not at all confident leaving my home because of my lung condition	
I sleep soundly	0	1	2	3	4	5	I don't sleep soundly because of my lung condition	
I have lots of energy	0	1	2	3	4	5	I have no energy at all	

Reference: Jones et al. ERJ 2009; 34 (3); 648-54.

FIGURE 2.3

© 2019 Global Initiative for Chronic Obstructive Lung Disease

TOTAL SCORE:



Modified MRC dyspnea scale

► MODIFIED MRC DYSPNEA SCALE^a

PLEASE TICK IN THE BOX THAT APPLIES TO YOU | ONE BOX ONLY | Grades 0 - 4

mMRC Grade 0.	I only get breathless with strenuous exercise.	<input type="checkbox"/>
mMRC Grade 1.	I get short of breath when hurrying on the level or walking up a slight hill.	<input type="checkbox"/>
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.	<input type="checkbox"/>
mMRC Grade 3.	I stop for breath after walking about 100 meters or after a few minutes on the level.	<input type="checkbox"/>
mMRC Grade 4.	I am too breathless to leave the house or I am breathless when dressing or undressing.	<input type="checkbox"/>

^a Fletcher CM. BMJ 1960; 2: 1662. © 2019 Global Initiative for Chronic Obstructive Lung Disease



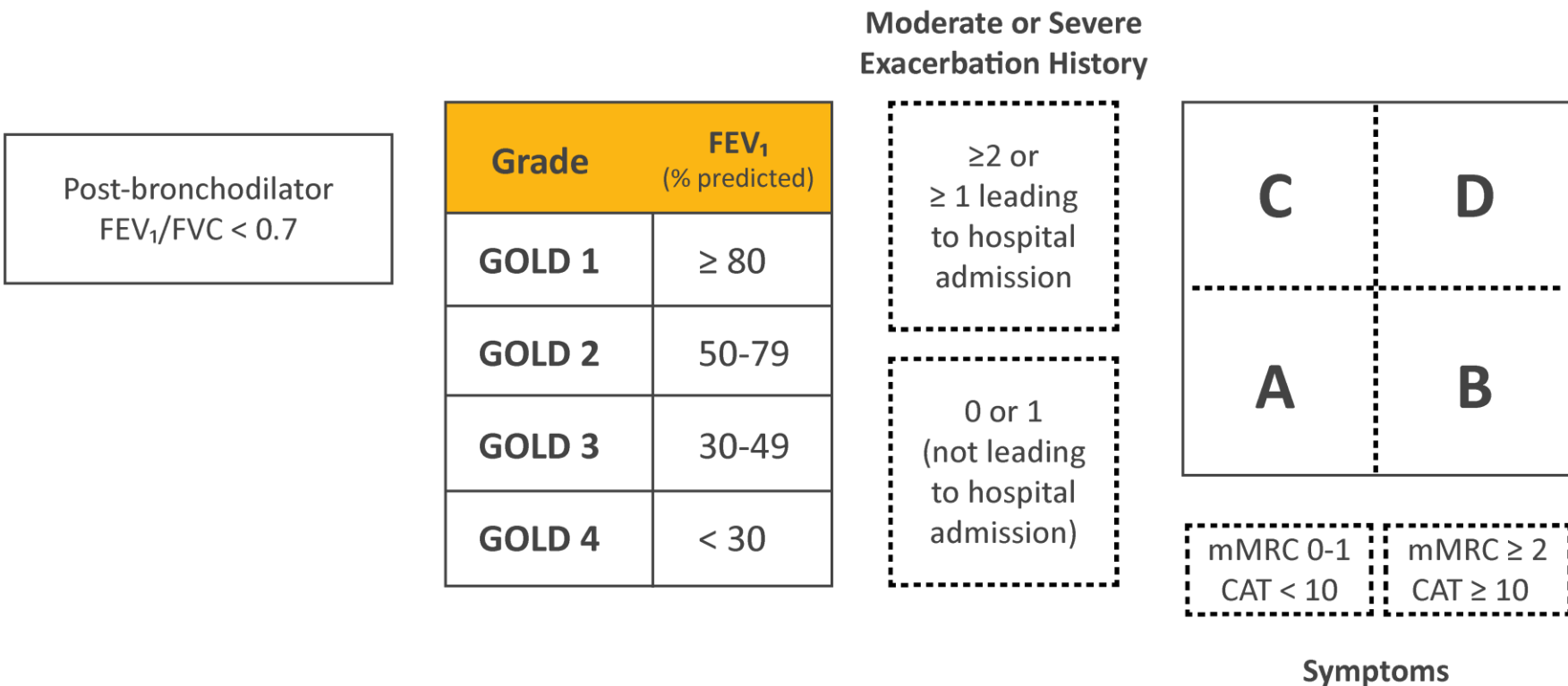
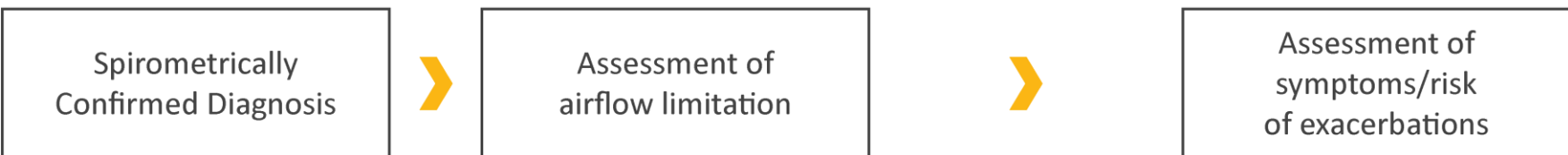
Assessment of Exacerbation Risk

- ▶ COPD exacerbations are defined as an acute worsening of respiratory symptoms that result in additional therapy.
- ▶ Classified as:
 - **Mild** (treated with SABDs only)
 - **Moderate** (treated with SABDs plus antibiotics and/or oral corticosteroids)
or
 - **Severe** (patient requires hospitalization or visits the emergency room).
Severe exacerbations may also be associated with acute respiratory failure.
- ▶ Blood eosinophil count may also predict exacerbation rates (in patients treated with LABA without ICS).



ABCD assessment tool

▶ THE REFINED ABCD ASSESSMENT TOOL





ABCD Assessment Tool

Example

- ▶ Consider two patients:
 - Both patients with $FEV_1 < 30\%$ of predicted
 - Both with CAT scores of 18
 - But, one with **0 exacerbations** in the past year and the other with **3 exacerbations** in the past year.
- ▶ Both would have been labelled **GOLD D** in the prior classification scheme.
- ▶ With the new proposed scheme, the subject with 3 exacerbations in the past year would be labelled **GOLD grade 4, group D**.
- ▶ The other patient, who has had no exacerbations, would be classified as **GOLD grade 4, group B**.



► ROLE OF SPIROMETRY

- **Diagnosis**
- **Assessment of severity of airflow obstruction (for prognosis)**
- **Follow-up assessment**
 - » Therapeutic decisions.
 - Pharmacological in selected circumstances (e.g., discrepancy between spirometry and level of symptoms).
 - Consider alternative diagnoses when symptoms are disproportionate to degree of airflow obstruction.
 - Non-pharmacological (e.g., interventional procedures).
 - » Identification of rapid decline.

TABLE 2.6



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Management of Stable COPD

▶ GOALS FOR TREATMENT OF STABLE COPD ▶

- Relieve Symptoms
- Improve Exercise Tolerance
- Improve Health Status



REDUCE SYMPTOMS

and

- Prevent Disease Progression
- Prevent and Treat Exacerbations
- Reduce Mortality



REDUCE RISK

TABLE 4.1



Management of Stable COPD

► IDENTIFY & REDUCE RISK FACTOR EXPOSURE

- Smoking cessation interventions should be actively pursued in all COPD patients **(Evidence A)**.
- Efficient ventilation, non-polluting cooking stoves and similar interventions should be recommended **(Evidence B)**.
- Clinicians should advise patients to avoid continued exposures to potential irritants, if possible **(Evidence D)**.

TABLE 4.3



Treatment of stable COPD

▶ INITIAL PHARMACOLOGICAL TREATMENT

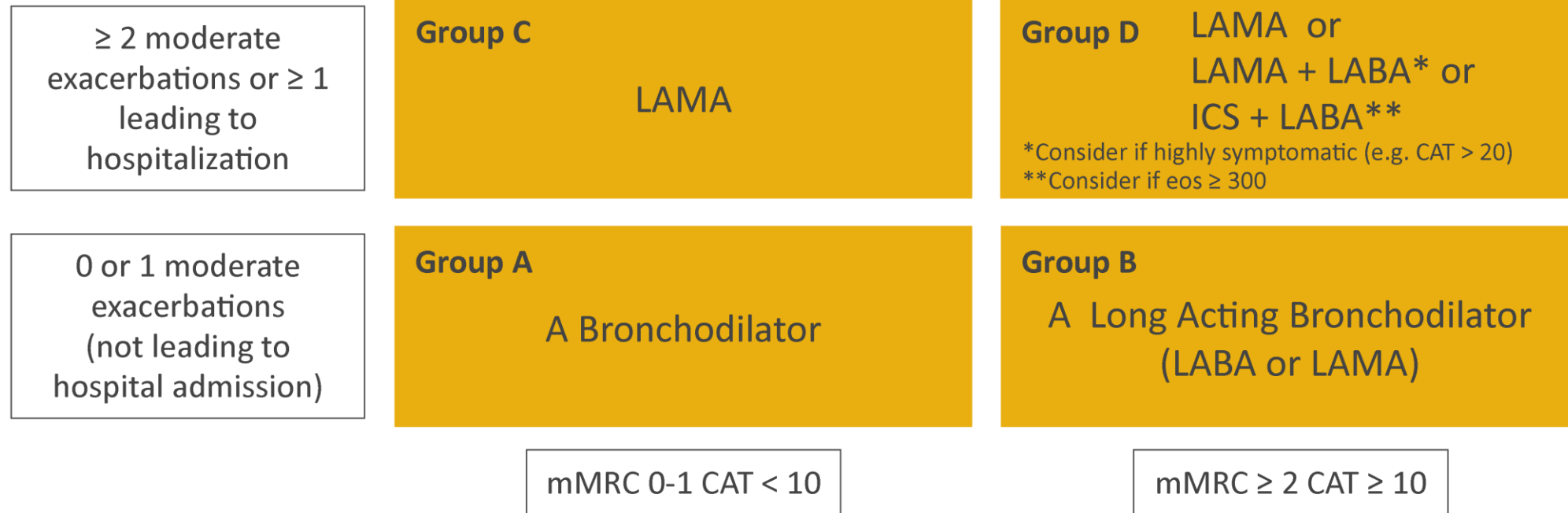


FIGURE 4.1

Definition of abbreviations: eos: blood eosinophil count in cells per microliter; mMRC: modified Medical Research Council dyspnea questionnaire; CAT™: COPD Assessment Test™.

Group A

INITIAL PHARMACOLOGICAL TREATMENT

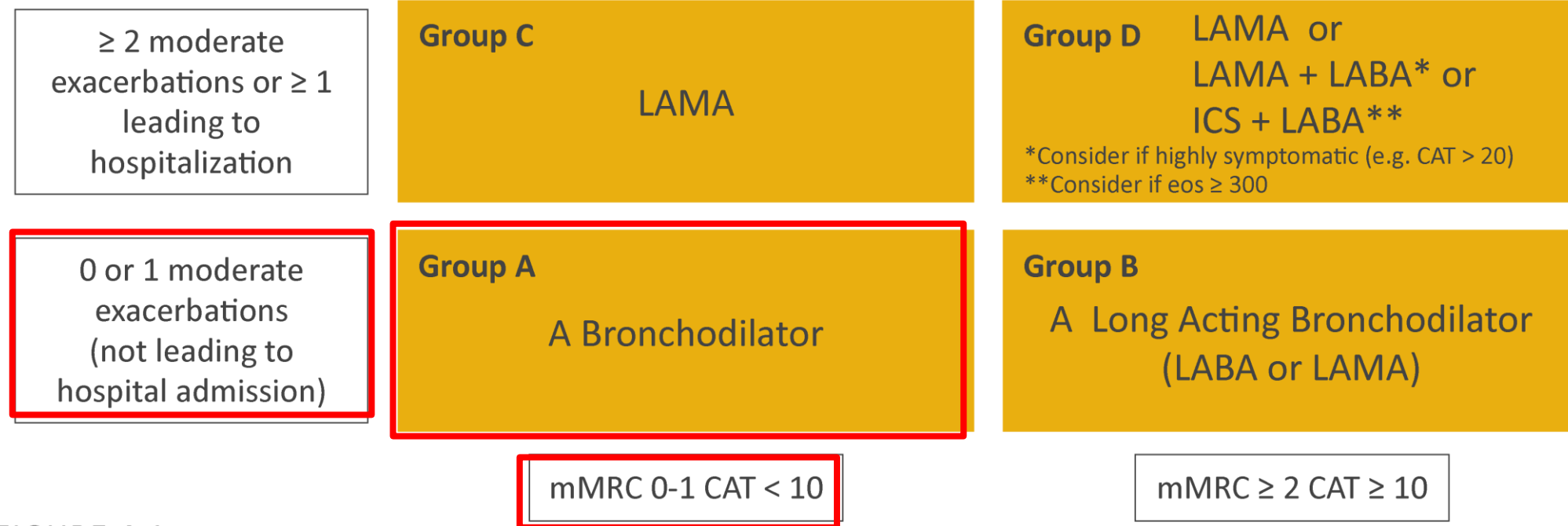


FIGURE 4.1

Group B

▶ INITIAL PHARMACOLOGICAL TREATMENT

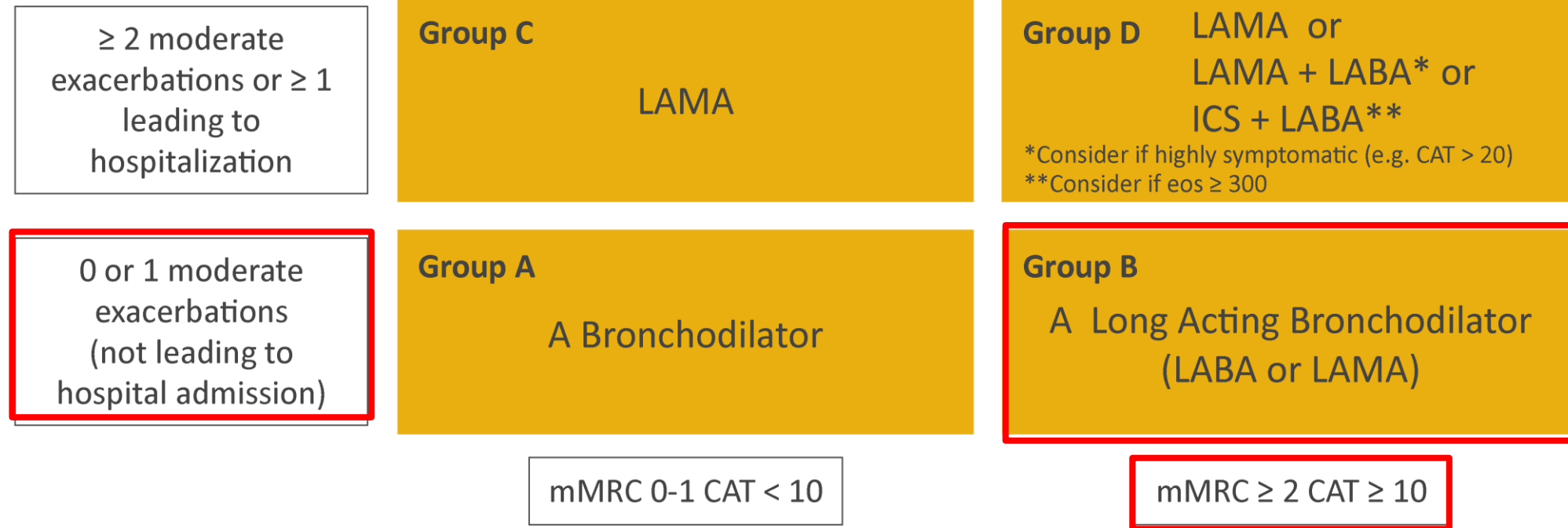


FIGURE 4.1

Group C

INITIAL PHARMACOLOGICAL TREATMENT

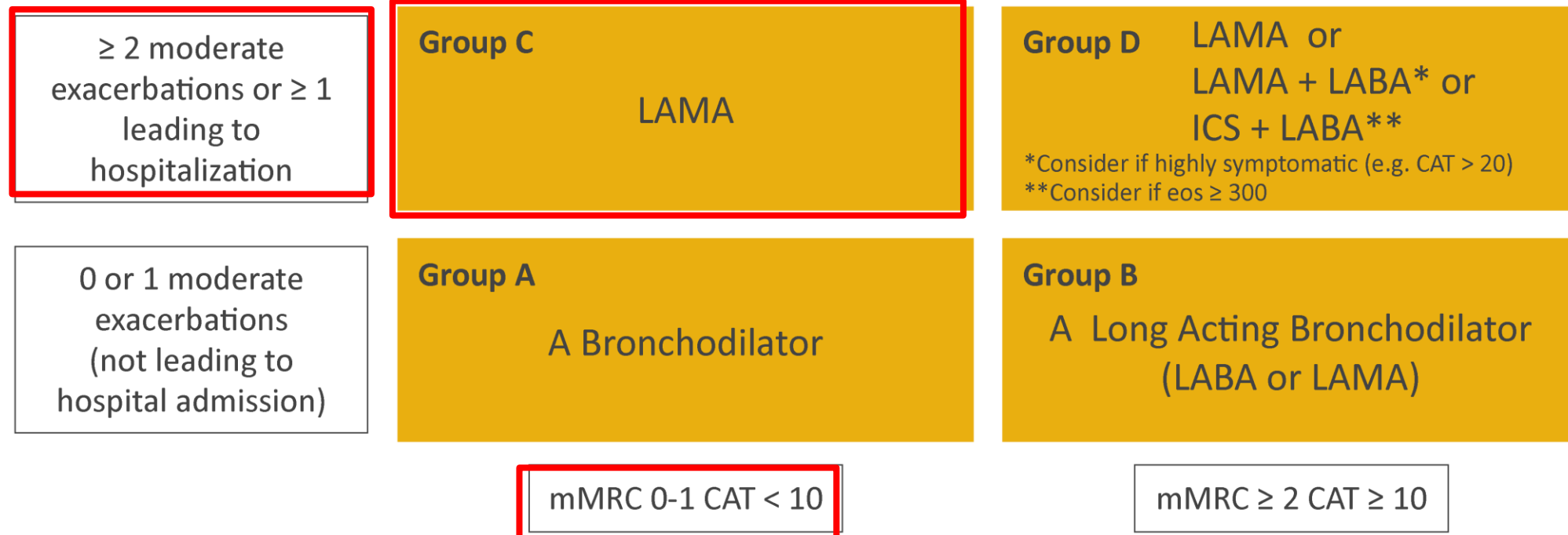


FIGURE 4.1

Group D

▶ INITIAL PHARMACOLOGICAL TREATMENT

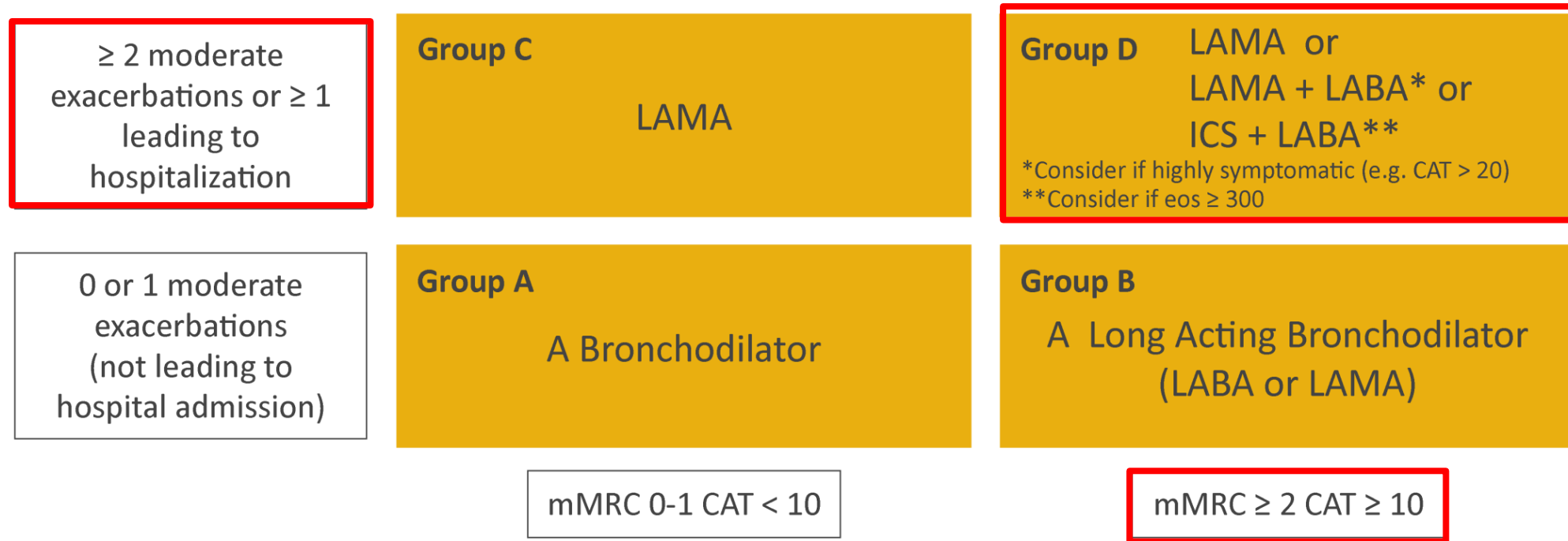


FIGURE 4.1

Treatment of stable COPD

MANAGEMENT CYCLE

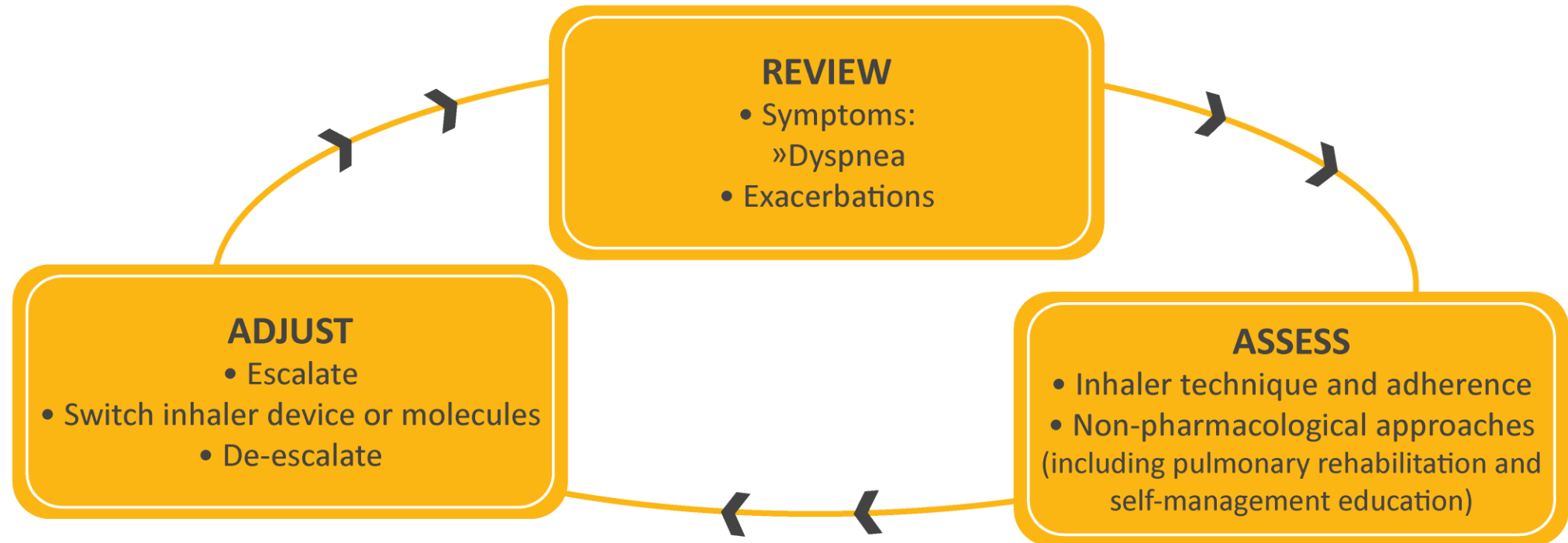


FIGURE 4.2



Treatment of stable COPD

Follow-up pharmacological treatment

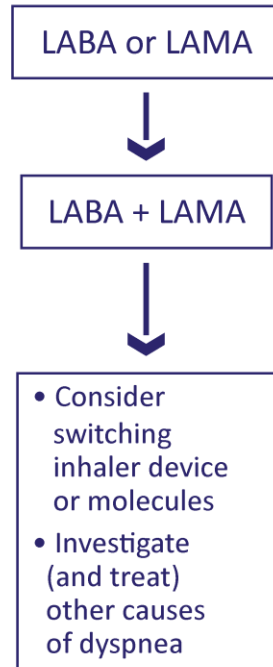
- ▶ A separate algorithm is provided for **FOLLOW-UP** treatment, where the management is still based on symptoms and exacerbations, but the recommendations do not depend on the patient's GOLD group at diagnosis.
- ▶ The response to treatment escalation should always be reviewed, and de-escalation should be considered if there is a lack of clinical benefit and/or side effects occur.
- ▶ De-escalation may also be considered in COPD patients receiving treatment who return with resolution of some symptoms that subsequently may require less therapy.
- ▶ Patients, in whom treatment modification is considered, in particular de-escalation, should be undertaken under close medical supervision.



FOLLOW-UP PHARMACOLOGICAL TREATMENT

1. IF RESPONSE TO INITIAL TREATMENT IS APPROPRIATE, MAINTAIN IT.
2. IF NOT:
 - ✓ Consider the predominant treatable trait to target (dyspnea or exacerbations)
 - Use exacerbation pathway if both exacerbations and dyspnea need to be targeted
 - ✓ Place patient in box corresponding to current treatment & follow indications
 - ✓ Assess response, adjust and review
 - ✓ These recommendations do not depend on the ABCD assessment at diagnosis

• DYSPNEA •



eos = blood eosinophil count (cells/ μ L)

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

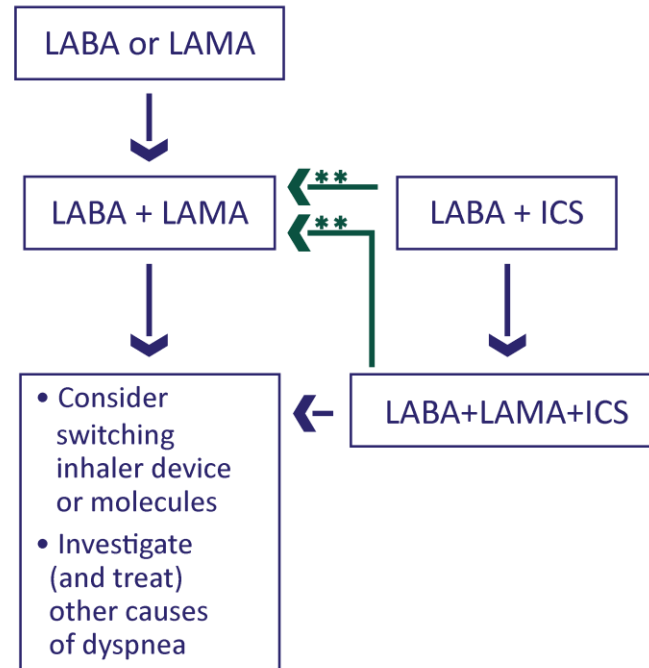
*** Consider de-escalation of ICS or switch if pneumonia, inappropriate original indication or lack of response to ICS*



FOLLOW-UP PHARMACOLOGICAL TREATMENT

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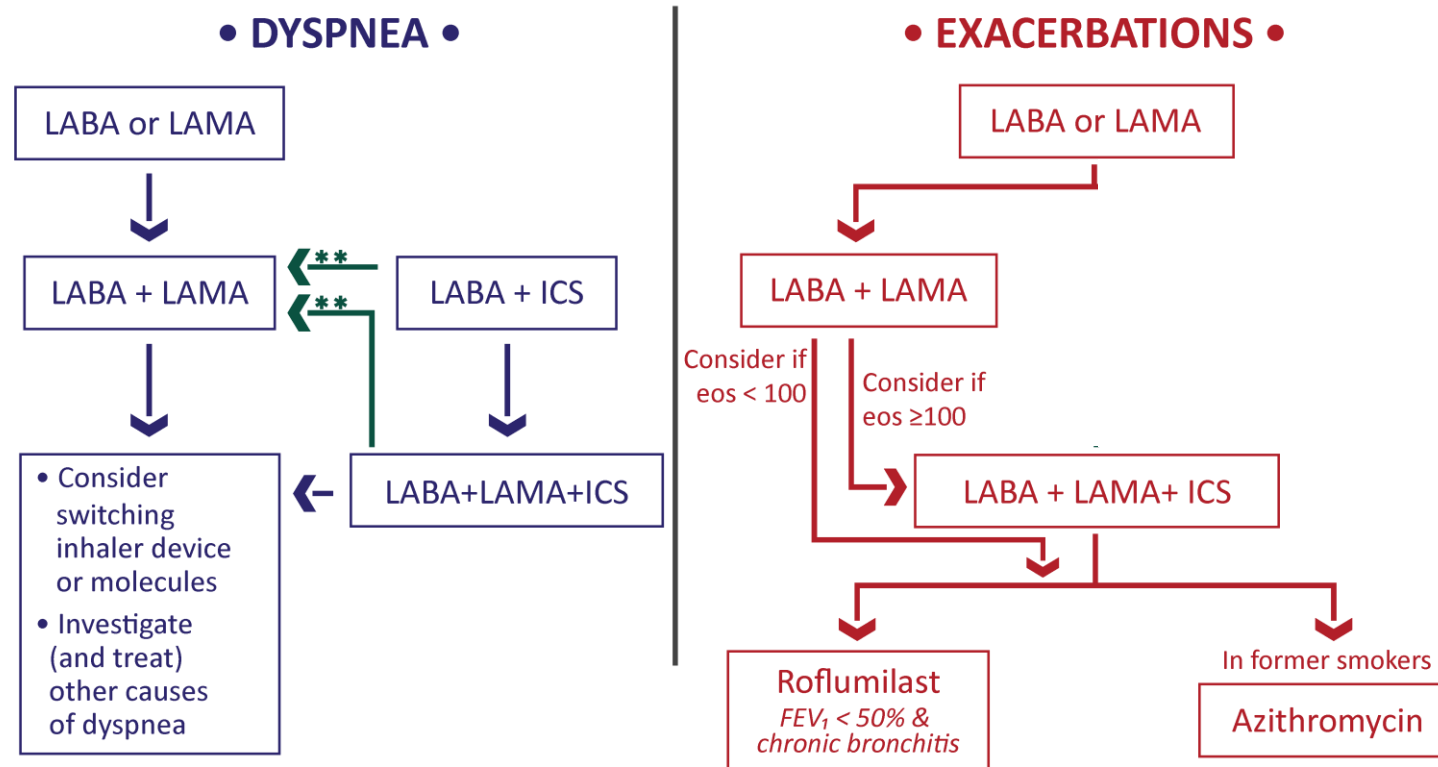
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FOLLOW-UP PHARMACOLOGICAL TREATMENT

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FIGURE 4.3

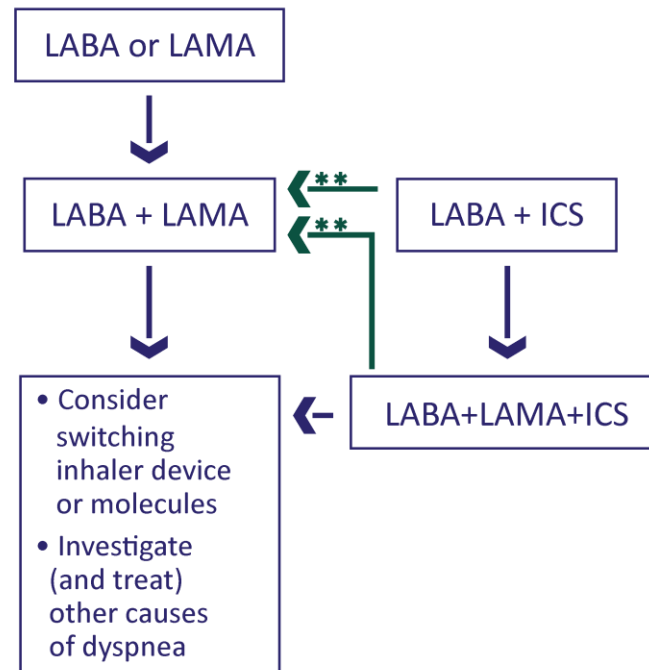


FOLLOW-UP PHARMACOLOGICAL TREATMENT

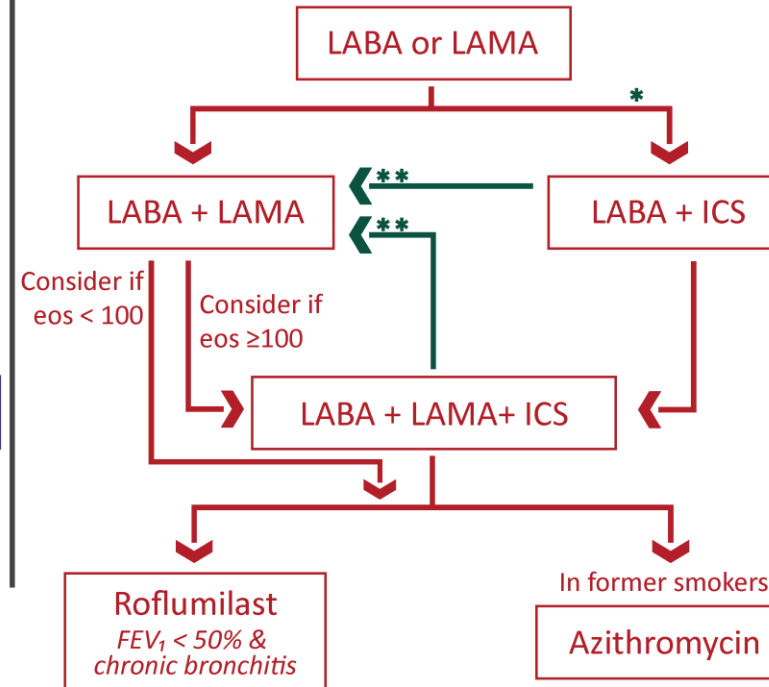
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 - ✓ Place patient in box corresponding to current treatment & follow indications
 - ✓ Assess response, adjust and review
 - ✓ These recommendations do not depend on the ABCD assessment at diagnosis

• DYSPNEA •



• EXACERBATIONS •



eos = blood eosinophil count (cells/ μ L)

* 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

FIGURE 4.3



Non-Pharmacological Treatment

- ▶ Education and self-management
- ▶ Physical activity
- ▶ Pulmonary rehabilitation programs
- ▶ Exercise training
- ▶ End of life and palliative care
- ▶ Nutritional support
- ▶ Vaccination
- ▶ Oxygen therapy



Non-pharmacological treatment

► NON-PHARMACOLOGIC MANAGEMENT OF COPD

PATIENT GROUP	ESSENTIAL	RECOMMENDED	DEPENDING ON LOCAL GUIDELINES
A	Smoking Cessation (can include pharmacologic treatment)	Physical Activity	Flu Vaccination
			Pneumococcal Vaccination
B-D	Smoking Cessation (can include pharmacologic treatment)	Physical Activity	Flu Vaccination
			Pneumococcal Vaccination
	Pulmonary Rehabilitation		

TABLE 4.8



Non-pharmacological treatment

► PRESCRIPTION OF SUPPLEMENTAL OXYGEN TO COPD PATIENTS ►

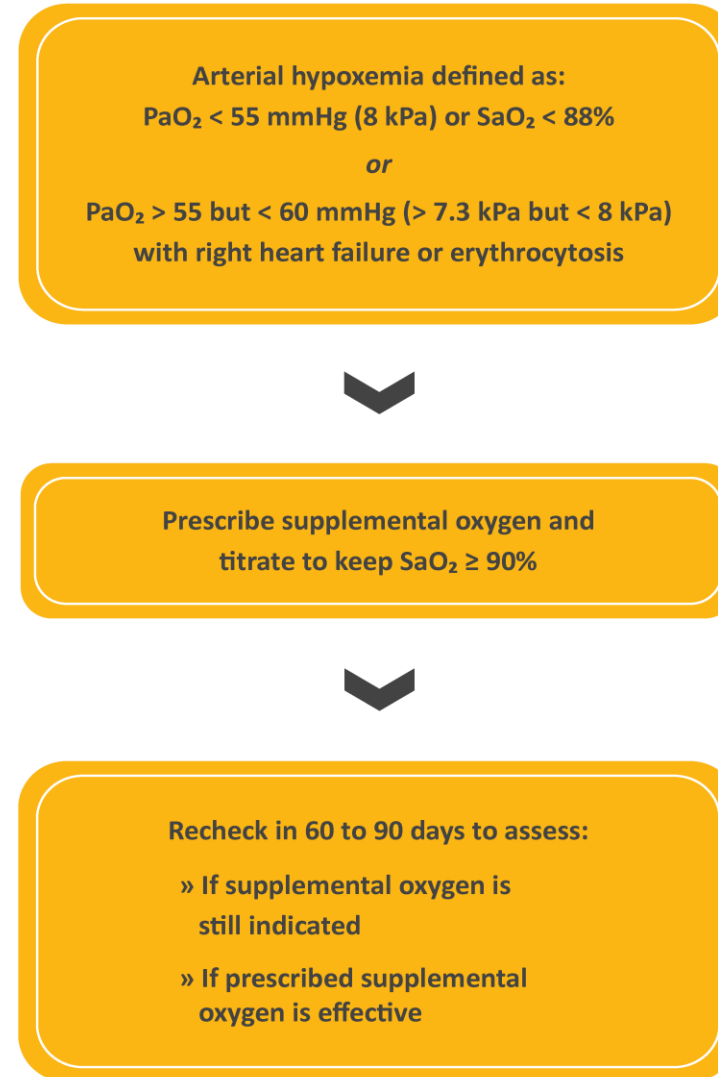
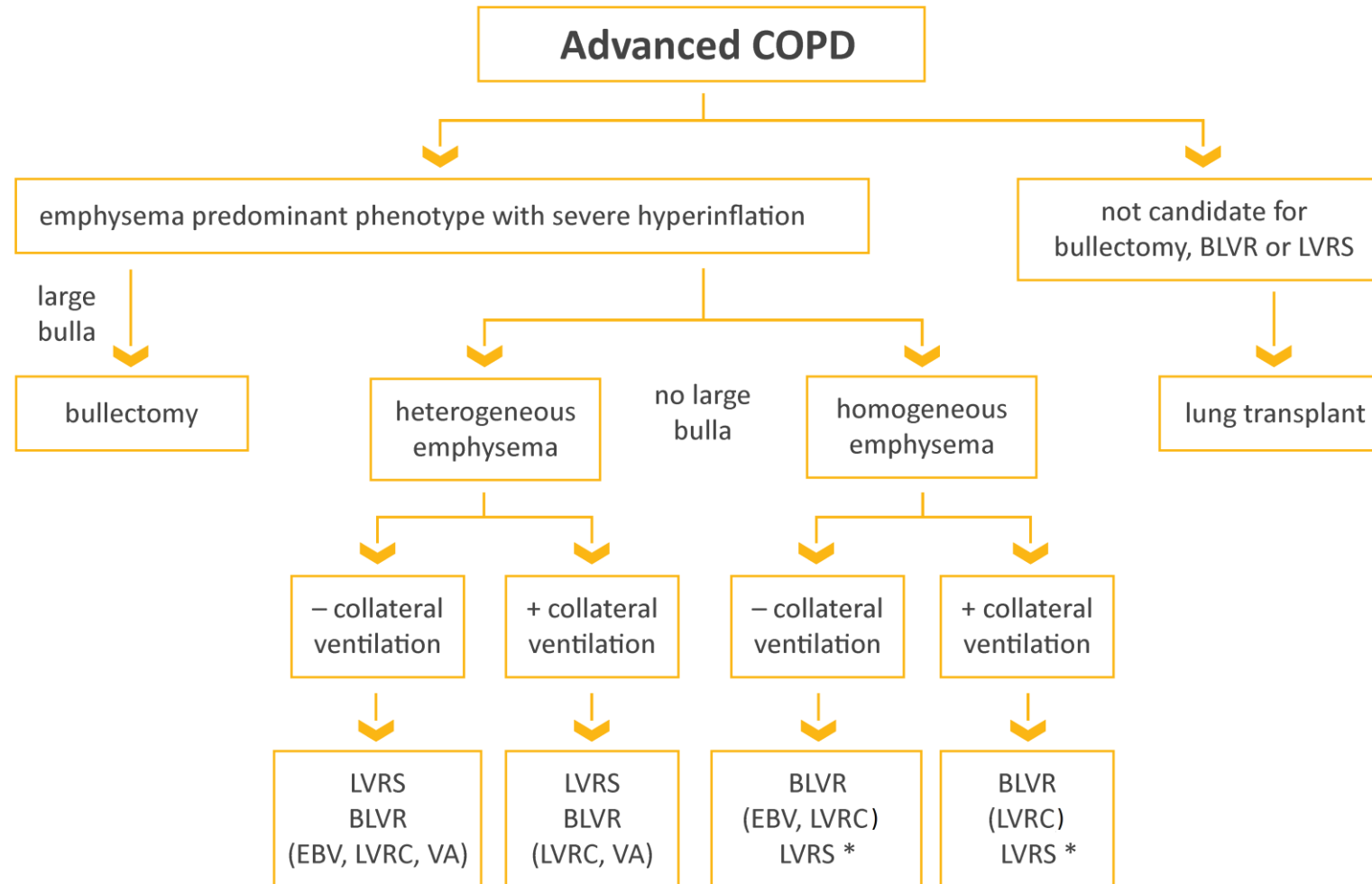


FIGURE 4.4



INTERVENTIONAL BRONCHOSCOPIC AND SURGICAL TREATMENTS FOR COPD

Overview of various therapies used to treat patients with COPD and emphysema worldwide. Note that all therapies are not approved for clinical care in all countries. Additionally, the effects of BLVR on survival or other long term outcomes or comparison to LVRS are unknown.



Definition of Abbreviations: BLVR, Bronchoscopic Lung Volume Reduction, EBV, endobronchial Valve, LVRS, Lung volume reduction surgery, LVRC, Lung volume reduction coil, VA, Vapor ablation

*at some but not all centers



Monitoring and Follow-up

Monitoring disease progression and development of complications and/or comorbidities

- ▶ **Measurements.** Decline in FEV_1 can be tracked by spirometry performed at least once a year.
- ▶ **Symptoms.** At each visit, information on symptoms since the last visit should be collected, including cough and sputum, breathlessness, fatigue, activity limitation, and sleep disturbances.
- ▶ **Exacerbations.** The frequency, severity, type and likely causes of all exacerbations should be monitored.
- ▶ **Imaging.** If there is a clear worsening of symptoms, imaging may be indicated.
- ▶ **Smoking status.** At each visit, the current smoking status and smoke exposure should be determined followed



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Management of Exacerbations

MANAGEMENT OF SEVERE BUT NOT LIFE-THREATENING EXACERBATIONS*

- Assess severity of symptoms, blood gases, chest radiograph.
- Administer supplemental oxygen therapy, obtain serial arterial blood gas, venous blood gas and pulse oximetry measurements.
- Bronchodilators:
 - » Increase doses and/or frequency of short-acting bronchodilators.
 - » Combine short-acting beta 2-agonists and anticholinergics.
 - » Consider use of long-active bronchodilators when patient becomes stable.
 - » Use spacers or air-driven nebulizers when appropriate.
- Consider oral corticosteroids.
- Consider antibiotics (oral) when signs of bacterial infection are present.
- Consider noninvasive mechanical ventilation (NIV).
- At all times:
 - » Monitor fluid balance.
 - » Consider subcutaneous heparin or low molecular weight heparin for thromboembolism prophylaxis.
 - » Identify and treat associated conditions (e.g., heart failure, arrhythmias, pulmonary embolism etc.).



Management of Exacerbations

▶ INDICATIONS FOR RESPIRATORY OR MEDICAL INTENSIVE CARE UNIT ADMISSION*

- Severe dyspnea that responds inadequately to initial emergency therapy.
- Changes in mental status (confusion, lethargy, coma).
- Persistent or worsening hypoxemia ($\text{PaO}_2 < 5.3 \text{ kPa}$ or 40 mmHg) and/or severe/worsening respiratory acidosis ($\text{pH} < 7.25$) despite supplemental oxygen and noninvasive ventilation.
- Need for invasive mechanical ventilation.
- Hemodynamic instability - need for vasopressors.

*Local resources need to be considered.

TABLE 5.4



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COPD and Comorbidities

OVERALL KEY POINTS (1 of 2):

- ▶ COPD often coexists with other diseases (comorbidities) that may have a significant impact on disease course.
- ▶ In general, the presence of comorbidities should not alter COPD treatment and comorbidities should be treated per usual standards regardless of the presence of COPD.
- ▶ Lung cancer is frequently seen in patients with COPD and is a main cause of death.
- ▶ Cardiovascular diseases are common and important comorbidities in COPD.



COPD and Comorbidities

OVERALL KEY POINTS (2 of 2):

- ▶ Osteoporosis and depression/anxiety are frequent, important comorbidities in COPD, are often under-diagnosed, and are associated with poor health status and prognosis.
- ▶ Gastroesophageal reflux (GERD) is associated with an increased risk of exacerbations and poorer health status.
- ▶ When COPD is part of a multimorbidity care plan, attention should be directed to ensure simplicity of treatment and to minimize polypharmacy.



COPD and Comorbidities

Some common comorbidities occurring in patients with COPD with stable disease:

- ▶ Cardiovascular disease (CVD)
- ▶ Heart failure
- ▶ Ischaemic heart disease (IHD)
- ▶ Arrhythmias
- ▶ Peripheral vascular disease
- ▶ Hypertension
- ▶ Osteoporosis
- ▶ Anxiety and depression
- ▶ COPD and lung cancer
- ▶ Metabolic syndrome and diabetes
- ▶ Gastroesophageal reflux (GERD)
- ▶ Bronchiectasis
- ▶ Obstructive sleep apnea

Σας ευχαριστώ!

Gold 2019

Μαρκάτος Μιλτιάδης
Πνευμονολόγος



ΕΝΩΣΗ ΠΝΕΥΜΟΝΟΛΟΓΩΝ ΕΛΛΑΔΑΣ

ΕΤΗΣΙΟ ΣΥΝΕΔΡΙΟ



30 Μαΐου - 2 Ιουνίου 2019

Αθήνα, Ξενοδοχείο Royal Olympic

Back up slides

Αναθεώρηση φαρμακευτικής αγωγής συντήρησης



Εμμένοντα συμπτώματα



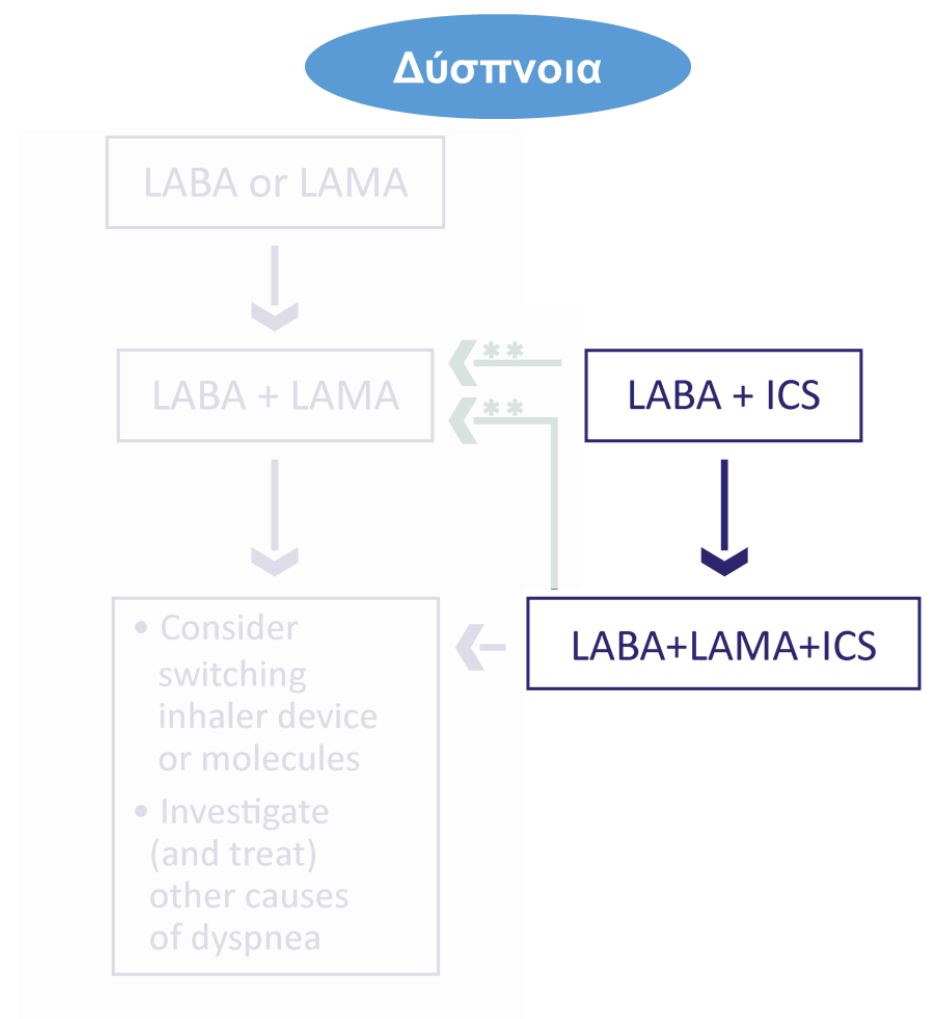
Επιδείνωση αναπνευστικής λειτουργίας



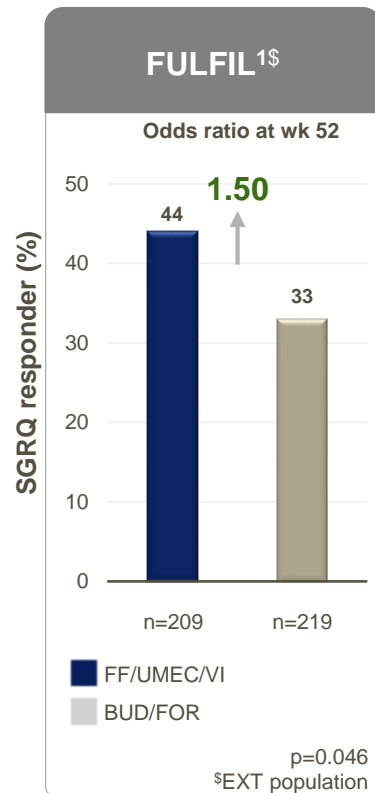
Μέτρα παρόξυνση/εις



Νοσηλεία



Τριπλή θεραπεία: ποσοστό ανταπόκρισης στην ποιότητα ζωής (SGRQ responder)*

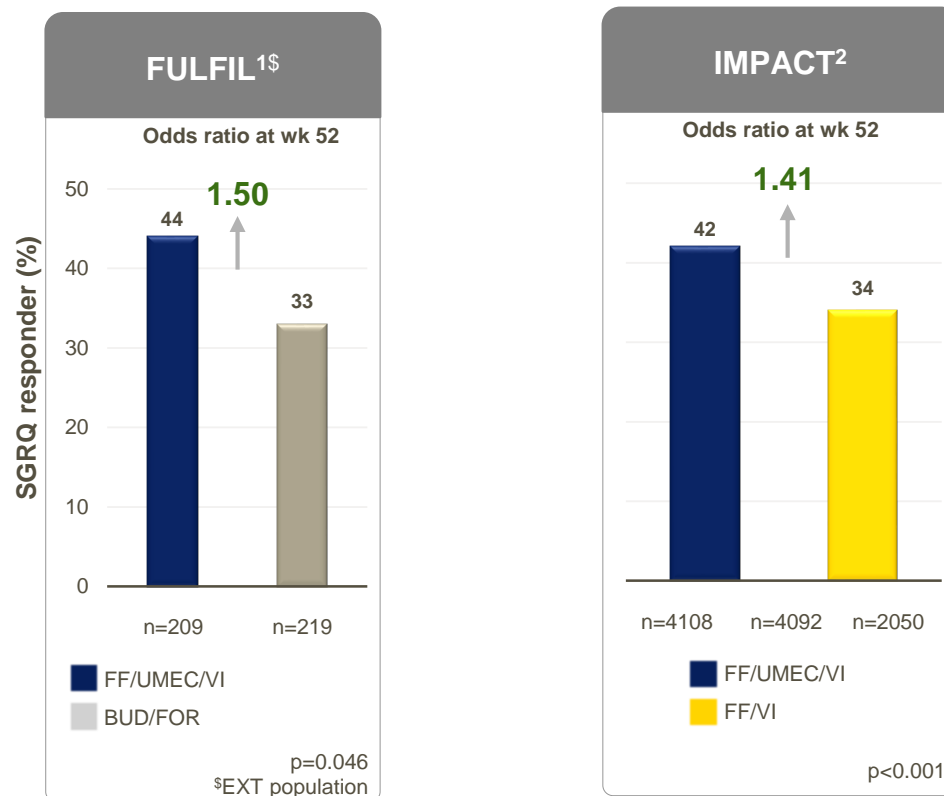


Καθώς δεν υπάρχουν head-to-head κλινικές μελέτες, δεν μπορούν να εξαχθούν συμπεράσματα διαφοράς στην αποτελεσματικότητα μεταξύ των δύο προϊόντων

*Data shown reflects ITT populations, unless otherwise specified
EXT: extension; ITT: intention to treat; OR: odds ratio

1. Lipson DA et al. Am J Respir Crit Care Med. 2017;196:438–446; 2. Lipson DA et al. N Engl J Med. 2018; 378:1671-1680; 3. Singh D et al. Lancet. 2016; 388: 963–973; 4. Vestbo J et al. Lancet. 2017; 389:1919–1929; 5. Papi A et al. Lancet. 2018; 391: 1076–1084

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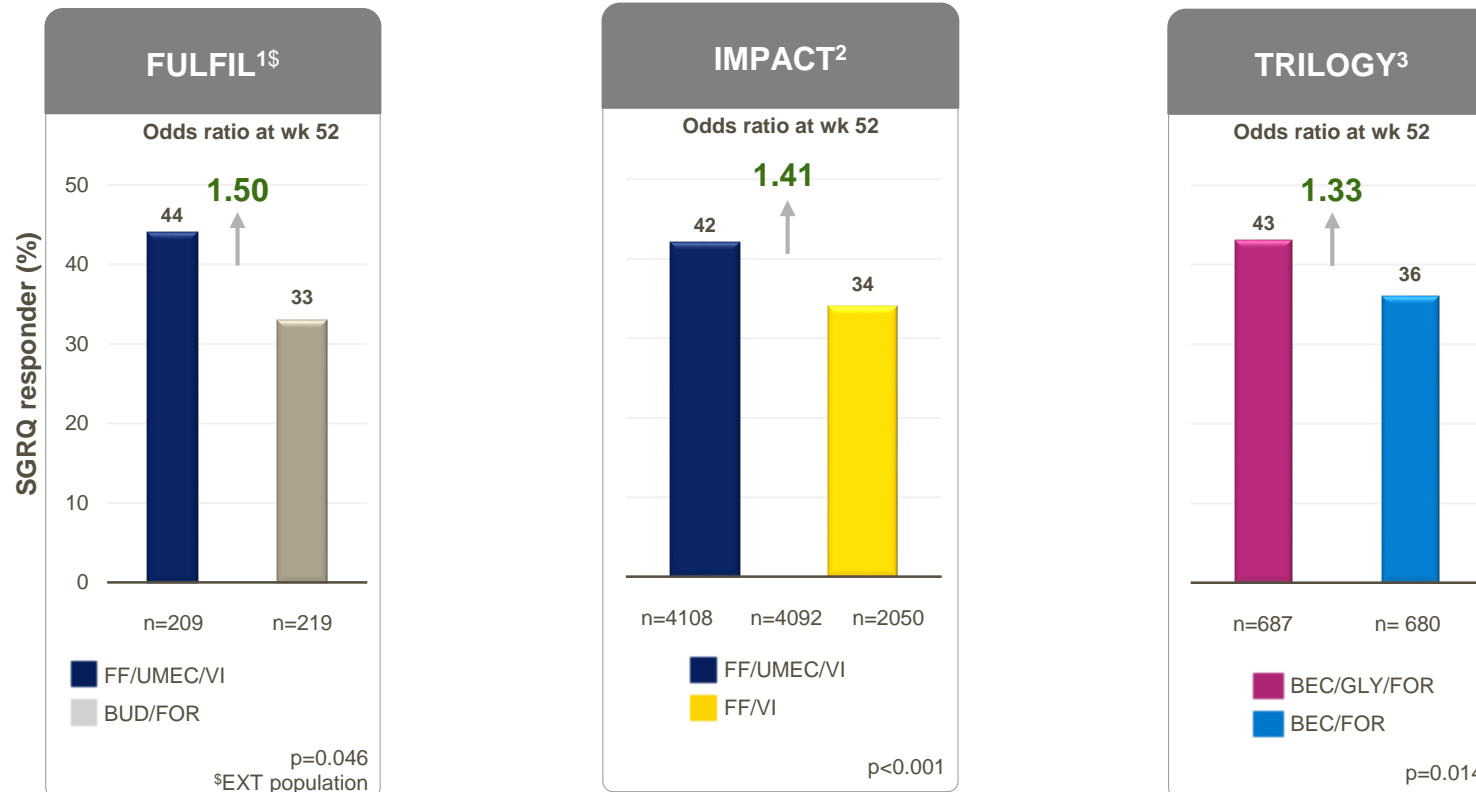


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Τριπλή θεραπεία: ποσοστό ανταπόκρισης στην ποιότητα ζωής (SGRQ responder)*



Καθώς δεν υπάρχουν head-to-head κλινικές μελέτες, δεν μπορούν να εξαχθούν συμπεράσματα διαφοράς στην αποτελεσματικότητα μεταξύ των δύο προϊόντων

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Αναθεώρηση φαρμακευτικής αγωγής συντήρησης



Εμμένοντα συμπτώματα



Επιδείνωση αναπνευστικής λειτουργίας

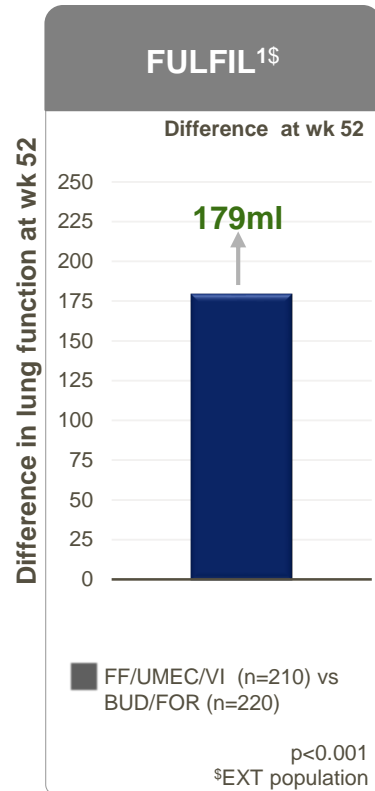


Μέτρα παρόξυνση/εις



Νοσηλεία

Τριπλή θεραπεία: αναπνευστική λειτουργία*

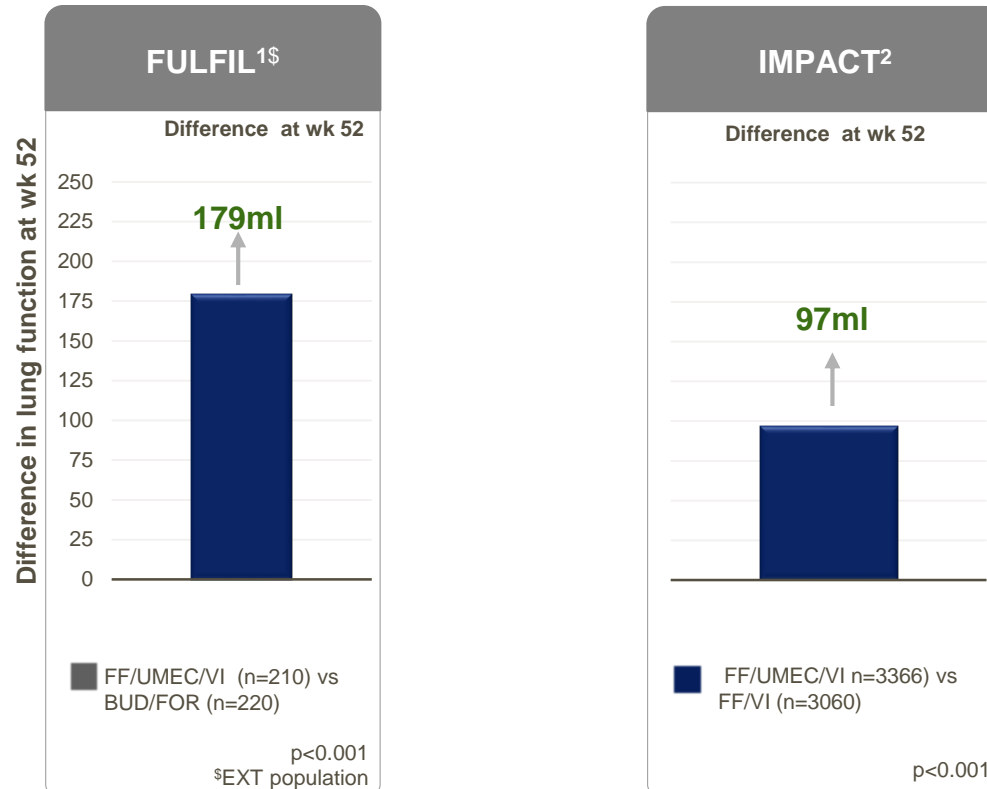


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Τριπλή θεραπεία: αναπνευστική λειτουργία*

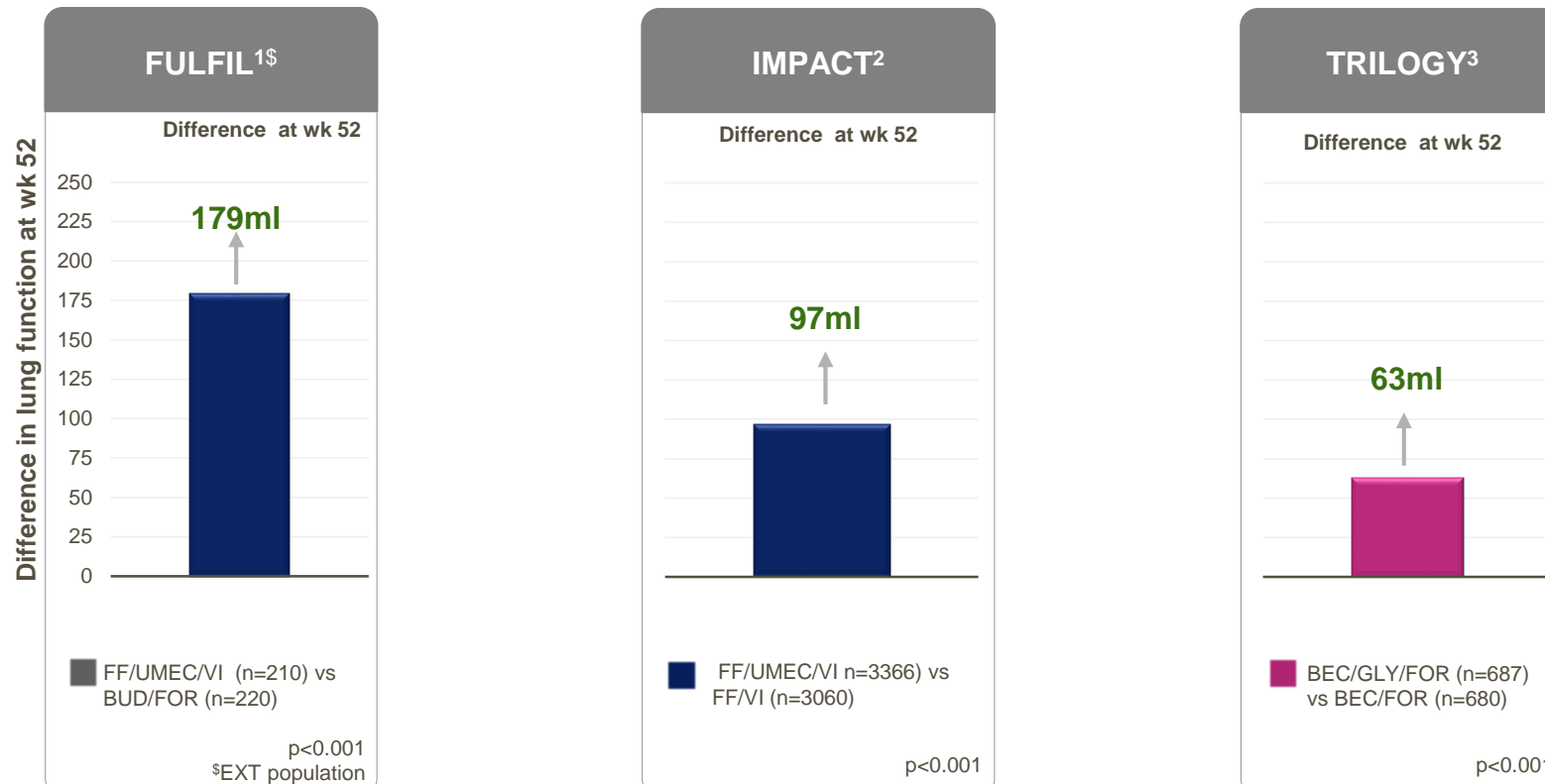


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Τριπλή θεραπεία: αναπνευστική λειτουργία*

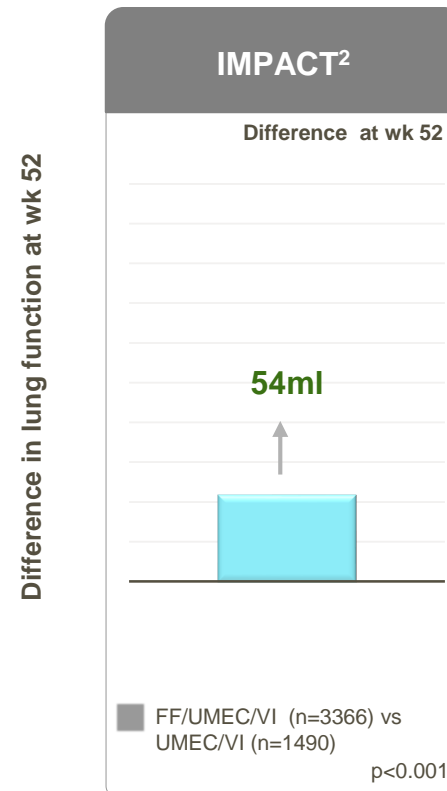


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Τριπλή θεραπεία: αναπνευστική λειτουργία*

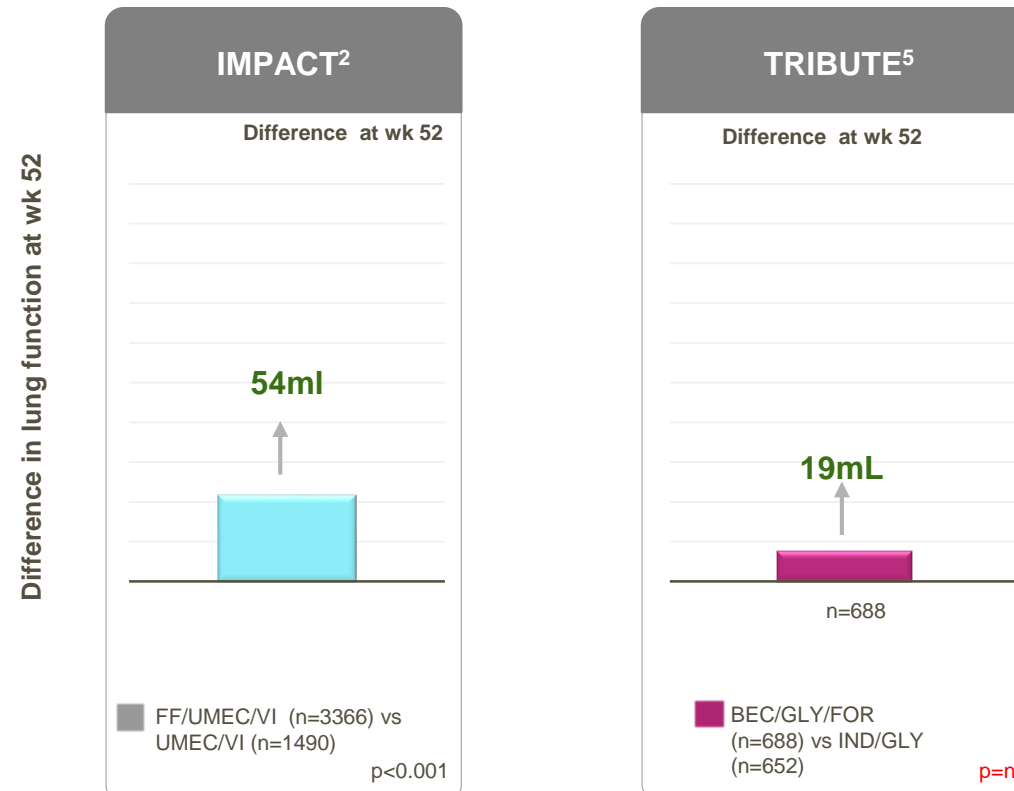


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Τριπλή θεραπεία: αναπνευστική λειτουργία*



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Αναθεώρηση φαρμακευτικής αγωγής συντήρησης



Εμμένοντα συμπτώματα



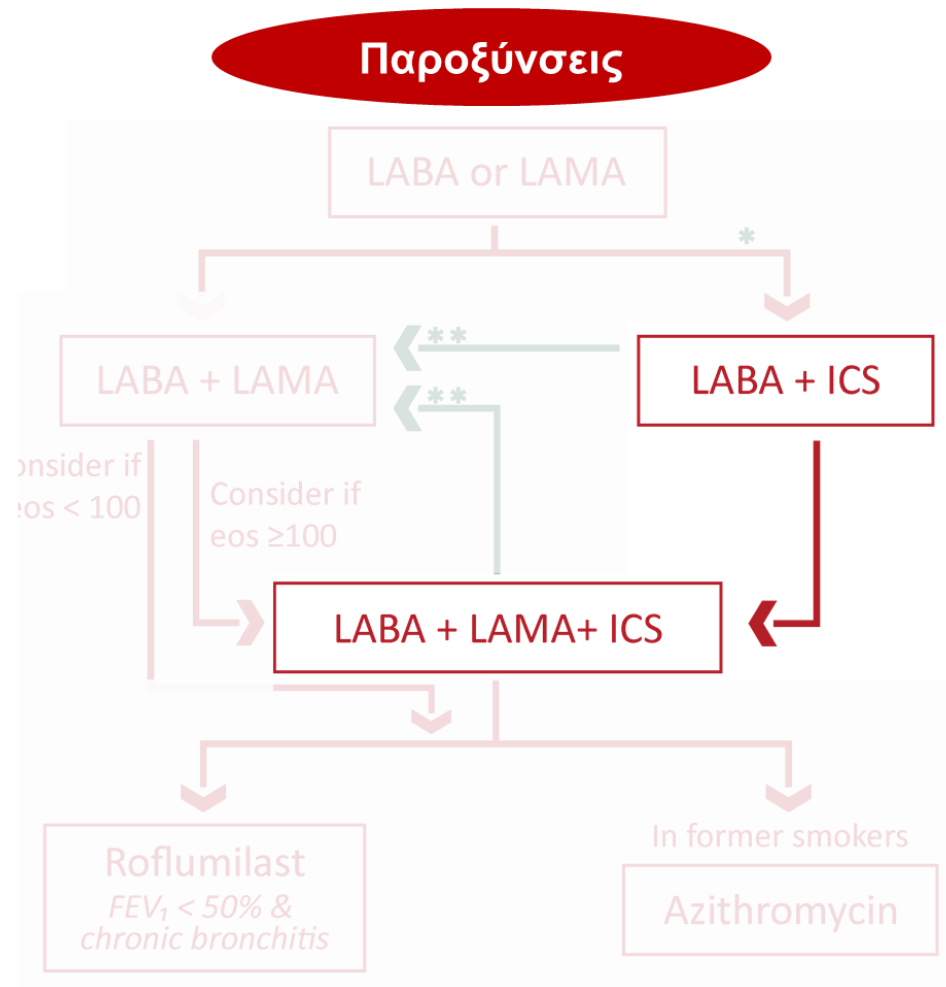
Επιδείνωση αναπνευστικής λειτουργίας



Μέτρα παρόξυνση/εις

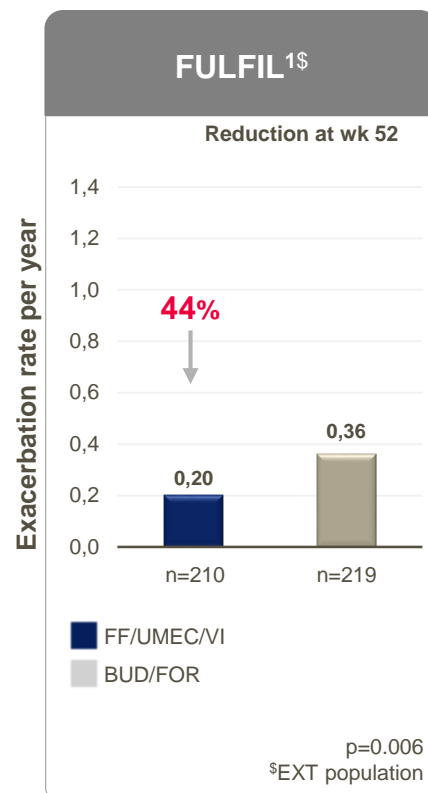


Νοσηλεία





Τριπλή θεραπεία: ποσοστό μείωσης μέτριων/σοβαρών παροξύνσεων*



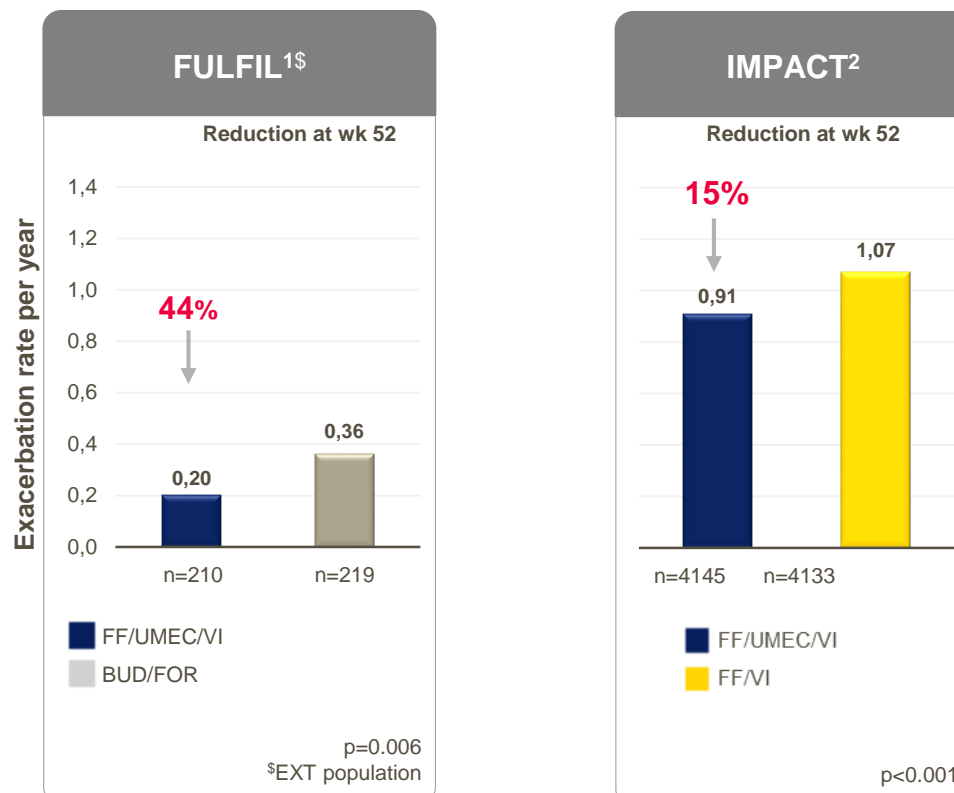
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Τριπλή θεραπεία: ποσοστό μείωσης μέτριων/σοβαρών παροξύνσεων*



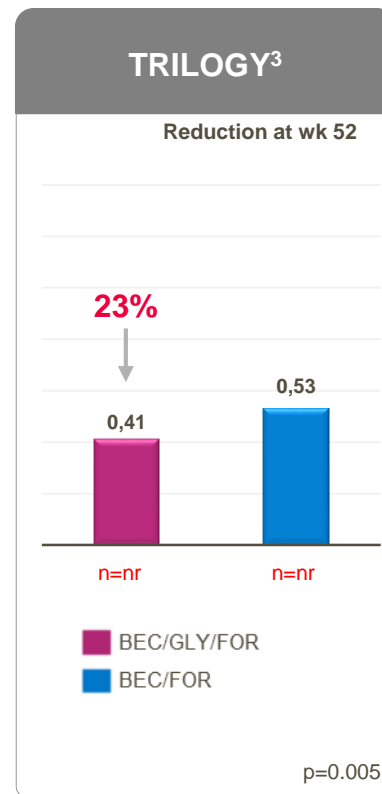
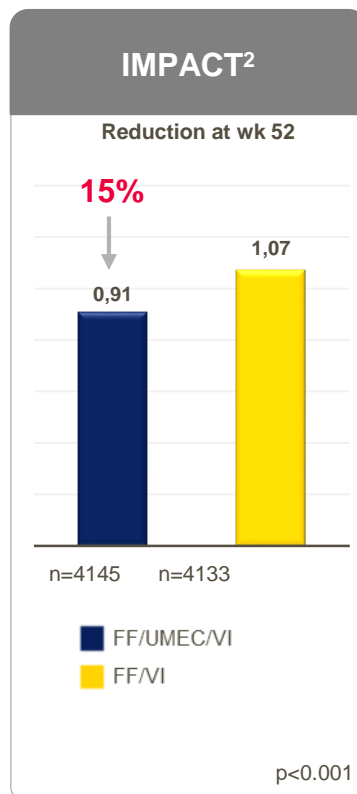
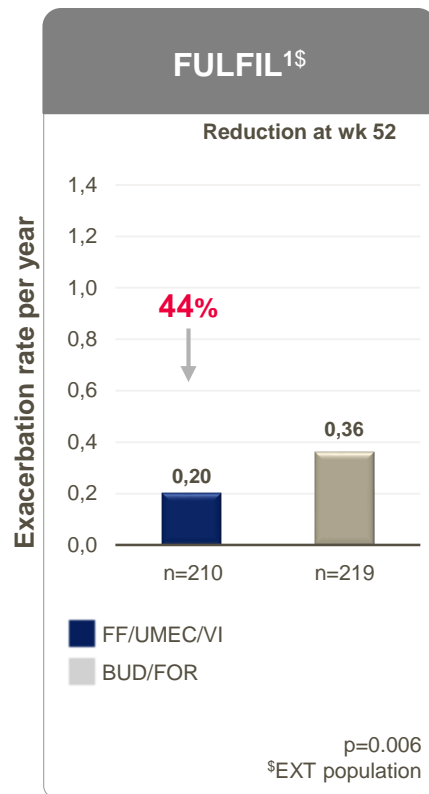
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Τριπλή θεραπεία: ποσοστό μείωσης μέτριων/σοβαρών παροξύνσεων*

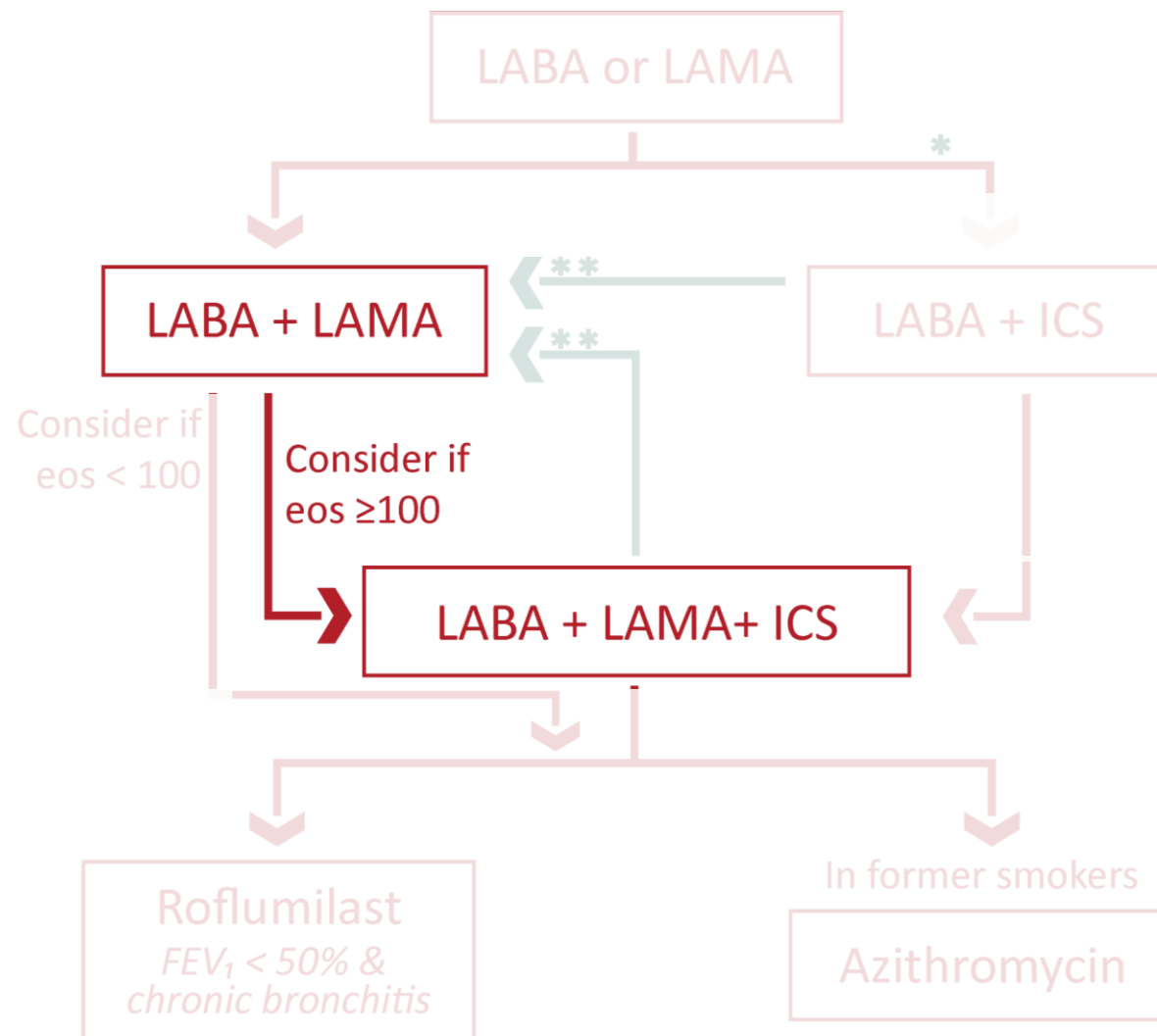


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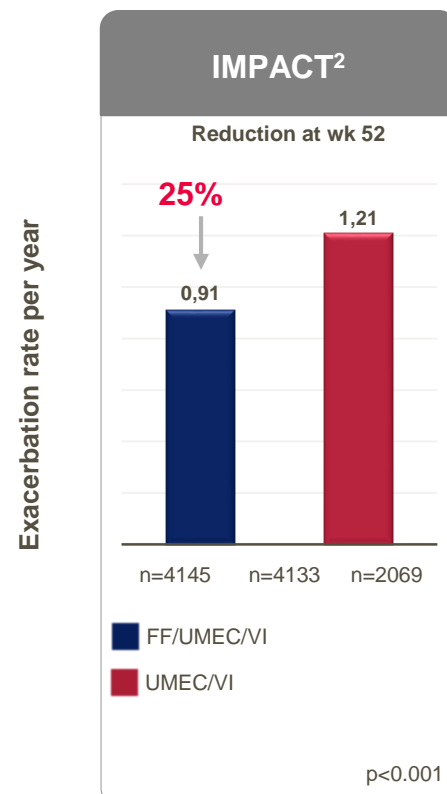
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Παροξύνσεις



Κλειστή τριπλή θεραπεία: ποσοστό μείωσης μέτριων/σοβαρών παροξύνσεων*

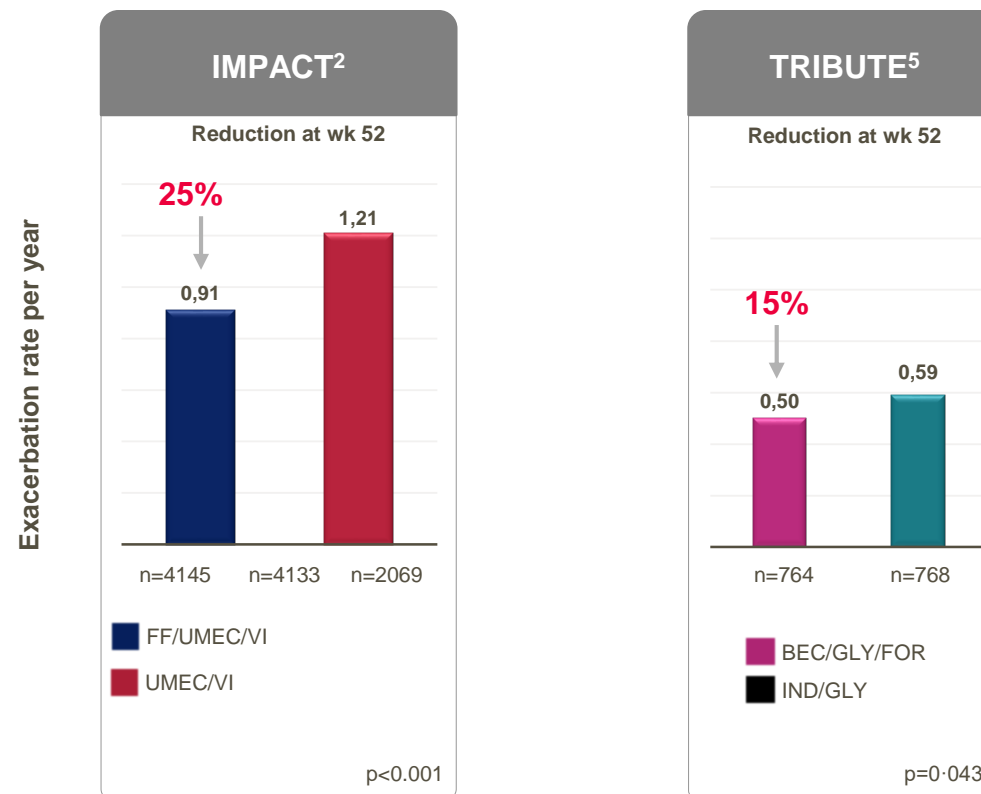


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Κλειστή τριπλή θεραπεία: ποσοστό μείωσης μέτριων/σοβαρών παροξύνσεων*



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