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COPD: Non-Pharmacologic Therapies

Darcy D. Marciniuk, MD FRCPC FCCP FCAHS

Professor of Respirology, Critical Care and Sleep Medicine, Royal University Hospital
Associate Vice-President Research, University of Saskatchewan
Saskatoon, SK, CANADA

UNIVERSITY OF SASKATCHEWAN

By the end of this presentation …

- Appreciate **non-pharmacologic interventions and therapies** available for the **effective management of COPD**
- Recognize **important clinical patient-centered approaches to therapy and care**
- Utilize effective **pharmacologic, non-pharmacologic and healthcare system interventions and strategies** to improve the care and outcomes for patients suffering from COPD

Conflict of Interest Disclosure

Consultancy

Alberta Lung Association, AstraZeneca, Boehringer-Ingelheim, Canadian Foundation for Healthcare Improvement, Chinese Committee of Health and Family Planning, GlaxoSmithKline, Health Canada, Lung Association of Saskatchewan, Mylan, Novartis, Saskatchewan Ministry of Health, Saskatchewan Health Authority, Yukon Health and Social Services

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Employee

University of Saskatchewan

COPD: Non-Pharmacologic Therapies

- Smoking cessation
- Vaccination
- Pulmonary Rehabilitation
- Self-Management, and Chronic Disease Management programs
- Actively managing advanced disease
  - appropriate end-of-life care
- Others: O_2, NIV, co-morbid/co-existent conditions, etc.
- Not forgetting about what matters most …
  - making the appropriate diagnosis
  - fully optimizing the puffers and the pills
  - not getting distracted …

Vaccinations

- **Recommend administering influenza vaccine annually to prevent acute exacerbations of COPD** [1,5,6]
  - reduced exacerbations compared with placebo. Weighted Mean Difference: -0.37, 95% CI -0.64 to -0.11 [p = 0.006] [1,2,3,4]
- **Suggest administering both the PCV13 and PPSV23** for all COPD patients ≥65 yrs [1,5,6]
  - **PPSV23 reduces community-acquired pneumonia** in COPD pts <65 yrs of age with an FEV_1 <40% predicted, and in those with co-morbidities
  - **PCV13** has demonstrated significant efficacy in **reducing bacteremia** and serious **invasive pneumococcal disease**

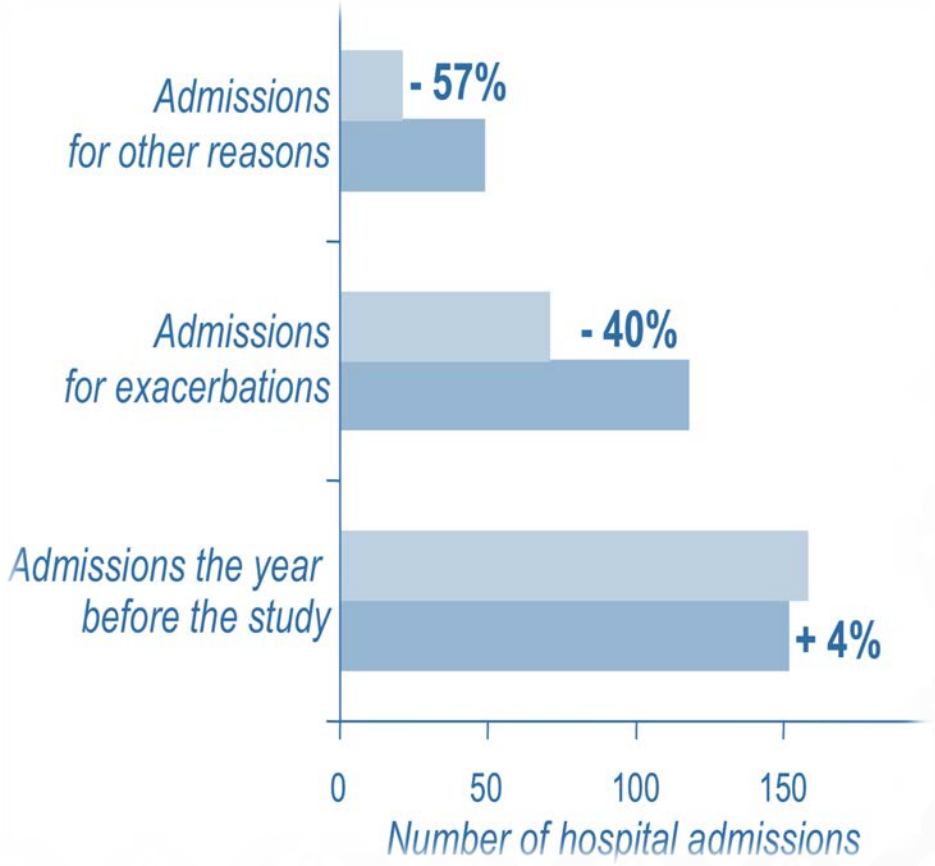
[1]Criner GJ, et al. *Chest* 2015; 147:894-942. [2]Poole P, et al. *Cochrane Database of Systematic Reviews* 2006. [3]Howells CH, et al. *Lancet* 1961; 1428-1432. [4]Wongsurakiat P, et al. *Chest* 2004; 2011-2020. [5]Bourbeau J, et al. *Can J Resp Crit Care Med* 2017; 1(4):222-241. [6]GOLD 2019

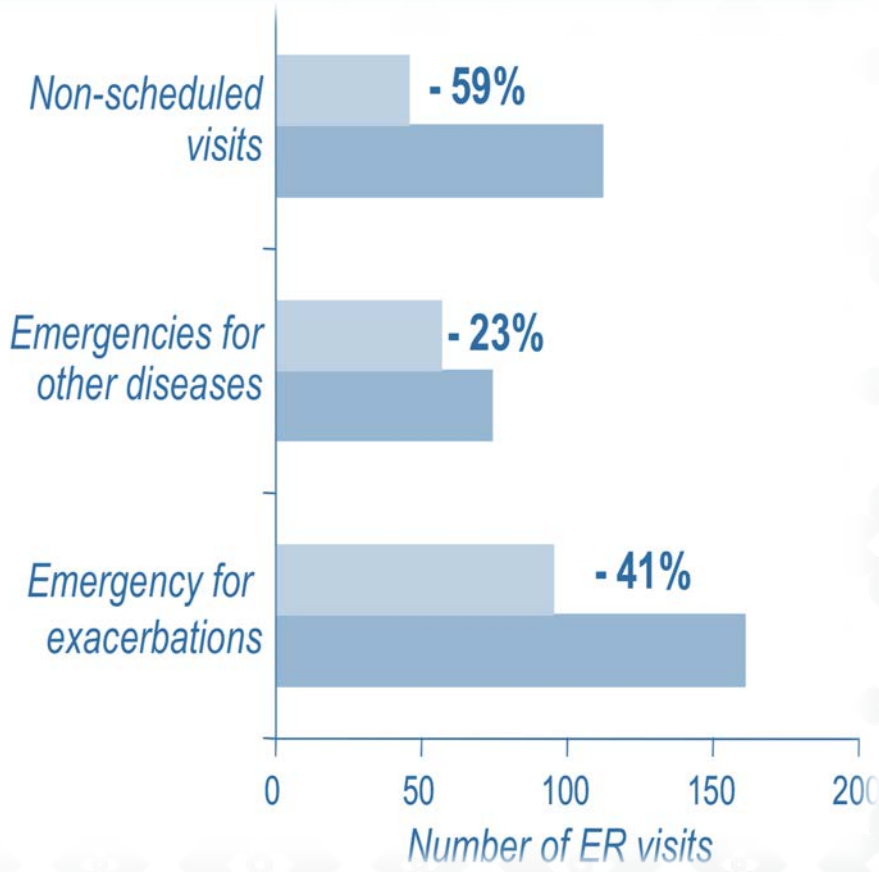
Pulmonary Rehabilitation

- **Meaningful and significant patient-centered benefits**
  - significantly improves exercise capacity and activity, reduces shortness of breath, enhances self-efficacy, and improves quality of life
  - significantly decreases AECOPD, hospitalizations and healthcare utilization
  - reduces anxiety and depression
- **Marked barriers and gaps**, starting with access
  - it is easier to get on renal dialysis!
  - ATS/ERS Guideline Statement ***'Enhancing Implementation, Utilization, and Delivery of Pulmonary Rehabilitation'*** - Increasing Awareness and Knowledge of PR, Increasing Patient Access to PR, Ensuring Quality of PR Programs, Future Research to Advance Evidence-based Policy in PR

Marciniuk DD, et al. *Can Resp J* 2010; 17: 159-168. Spruit MA, et al. *Am Resp J Crit Care Med* 2013; 188:e13-64. Criner GL, et al. *Chest* 2015; 147:894-942. Rochester CL, et al. *Am J Resp Crit Care Med* 2015; 192:1373-1386.

Comprehensive COPD Management





Bourbeau J, et al. *Arch Int Med* 2003, 163:585-91. Canadian Thoracic Society. *Can Respir J* 2004; 11(Suppl B): 7B-59B

Annals of Internal Medicine | ORIGINAL RESEARCH

A Comprehensive Care Management Program to Prevent Chronic Obstructive Pulmonary Disease Hospitalizations

A Randomized, Controlled Trial

Vincent S. Fan, MD, MPH; J. Michael Gaziano, MD, MPH; Robert Lew, PhD; Jean Bourbeau, MD, MSc; Sandra G. Adams, MD, MS; Sarah Leatherman, MS; Soe Soe Thwin, PhD, MS; Grant D. Huang, PhD, MPH; Richard Robbins, MD; Peruvemba S. Sriram, MD; Amir Sharafkhaneh, MD; M. Jeffery Mador, MD; George Sarosi, MD; Ralph J. Panos, MD; Padmashri Rastogi, MD; Todd H. Wagner, PhD; Steven A. Mazzuca, PhD; Colleen Shannon, MPH; Cindy Colling, RPH, MS; Matthew H. Liang, MD, MPH; James K. Stoller, MD, MS; Louis Fiore, MD, MPH; and Dennis E. Niewoehner, MD

Background: Improving a patient's ability to self-monitor and manage changes in chronic obstructive pulmonary disease (COPD) symptoms may improve outcomes.

Objective: To determine the efficacy of a comprehensive care management program (CCMP) in reducing the risk for COPD hospitalization.

Design: A randomized, controlled trial comparing CCMP with guideline-based usual care. (ClinicalTrials.gov registration number: NCT00395083)

Setting: 20 Veterans Affairs hospital-based outpatient clinics.

Participants: Patients hospitalized for COPD in the past year.

Intervention: The CCMP included COPD education during 4 individual sessions and 1 group session, an action plan for identification and treatment of exacerbations, and scheduled proactive telephone calls for case management. Patients in both the intervention and usual care groups received a COPD informational booklet; their primary care providers received a copy of COPD guidelines and were advised to manage their patients according to these guidelines. Patients were randomly assigned, stratifying by site based on random, permuted blocks of variable size.

Measurements: The primary outcome was time to first COPD hospitalization. Staff blinded to study group performed telephone-based assessment of COPD exacerbations and hospitalizations, and all hospitalizations were blindly adjudicated. Secondary outcomes included non-COPD health care use, all-cause mortality, health-related quality of life, patient satisfaction, disease knowledge, and self-efficacy.

Results: Of the eligible patients, 209 were randomly assigned to the intervention group and 217 to the usual care group. Citing serious safety concerns, the data monitoring committee terminated the intervention before the trial's planned completion after 426 (44%) of the planned total of 960 patients were enrolled. Mean follow-up was 250 days. When the study was stopped, the 1-year cumulative incidence of COPD-related hospitalization was 27% in the intervention group and 24% in the usual care group (hazard ratio, 1.13 [95% CI, 0.70 to 1.80]; $P = 0.62$). There were 28 deaths from all causes in the intervention group versus 10 in the usual care group (hazard ratio, 3.00 [CI, 1.46 to 6.17]; $P = 0.003$). Cause could be assigned in 27 (71%) deaths. Deaths due to COPD accounted for the largest difference: 10 in the intervention group versus 3 in the usual care group (hazard ratio, 3.60 [CI, 0.99 to 13.08]; $P = 0.053$).

Limitations: Available data could not fully explain the excess mortality in the intervention group. Ability to assess the quality of the educational sessions provided by the case managers was limited.

Conclusion: A CCMP in patients with severe COPD had not decreased COPD-related hospitalizations when the trial was stopped prematurely. The CCMP was associated with unanticipated excess mortality, results that differ markedly from similar previous trials. A data monitoring committee should be considered in the design of clinical trials involving behavioral interventions.

Primary Funding Source: Veterans Affairs Cooperative Study Program.

Ann Intern Med. 2012;156:673-683. www.annals.org
For author affiliations, see end of text.

Fan VS, et al. *Ann Intern Med* 2012; 156:673-683

Unexpected Results!

- **study terminated early** (mean follow-up 250 days) - **increased mortality** in CC group [28 deaths vs 10 in UC group; p = 0.003]
  - 'COPD' deaths accounted for the difference
- hospitalization 27% CC group vs 24% UC group [p=0.62]
- **delay in starting prednisone treatment** (6.4 days CC vs 7.7 days UC; p = 0.48) and **delay in starting antibiotic treatment** (7.0 days CC vs 6.8 days UC ; p = 0.84)
  - **fundamental failure of the intervention!**
- **staff had varied backgrounds, with [only] 3 days of 'training'**
  - patients with complex COPD and high disease burden require specialized attention and expertise

Fan VS, et al. *Ann Intern Med* 2012; 156:673-683

Benefits of Education

- Provides Group Support
- Improves Self-Confidence
- Addresses Family Concerns
- Provides Disease Specific Information
- Improves Risk Factor Awareness
- Helps with Lifestyle Changes

Benefits of Exercise

- Lowers Blood Pressure
- Improves Cholesterol Profile
- Assists with Weight Control
- Helps with Diabetes Prevention and Management
- Improves Quality of Life
- Decreases Stress Level
- Increases Energy Level
- Strengthens Bones

Benefits of Self-management

- Builds confidence
- Promotes ability to take control
- Provides practise on action planning
- Develops problem solving abilities
- Improves symptom management

CDM Program Goals

To develop and implement coordinated, effective and efficient care for people with chronic conditions

To optimize care of people by promoting a team approach and enhanced self-management of disease

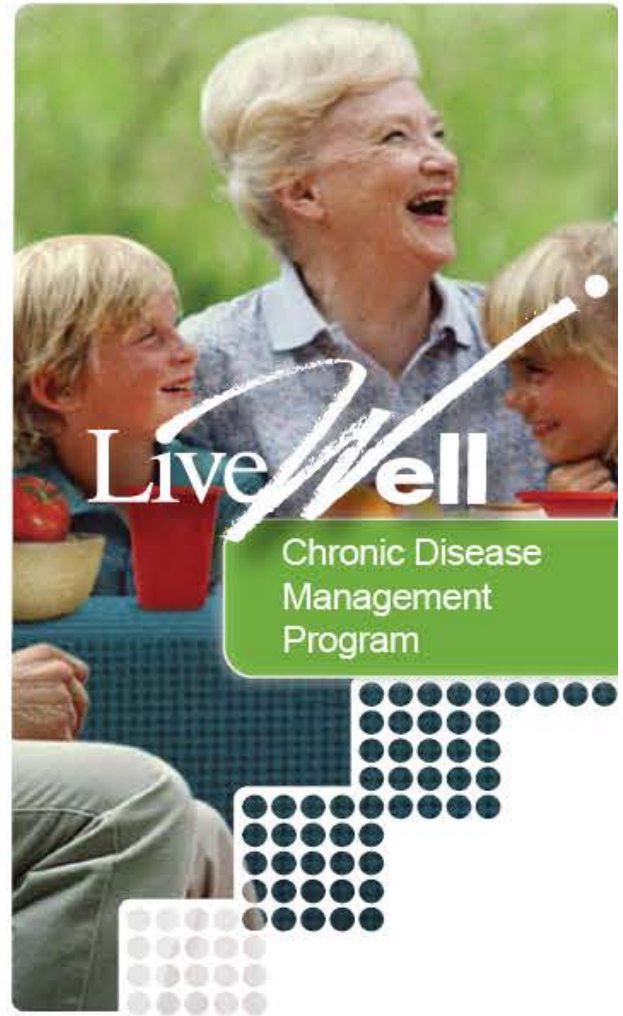
To promote inter-professional collaboration and education

LiveWell
Optimizing Chronic Disease Management

For more information about the CDM Program, please contact:

Chronic Disease Management Program
Royal University Hospital,
103 Hospital Drive
Saskatoon SK S7N 0W8
Office: (306) 655-LIVE
(306) 655-5483
Facsimile: (306) 655-6758
live-well@saskatoonhealthregion.ca

PROGRAM OF
Saskatoon Health Region



LiveWell
Chronic Disease Management Program

Optimizing Chronic Disease Management

PROGRAM OF
Saskatoon Health Region

Group Exercise and Rehabilitation	Disease-Specific Management	Patient Self-Management
• Community-based exercise and rehabilitation programming • Group education • Group and social support	• Inter-professional team working with the patient, family, and Family Physician • Evidence-based optimal care delivery	• Individualized plan of action • Patient-led group support “LiveWell with Chronic Conditions” • Enhanced self-management skills

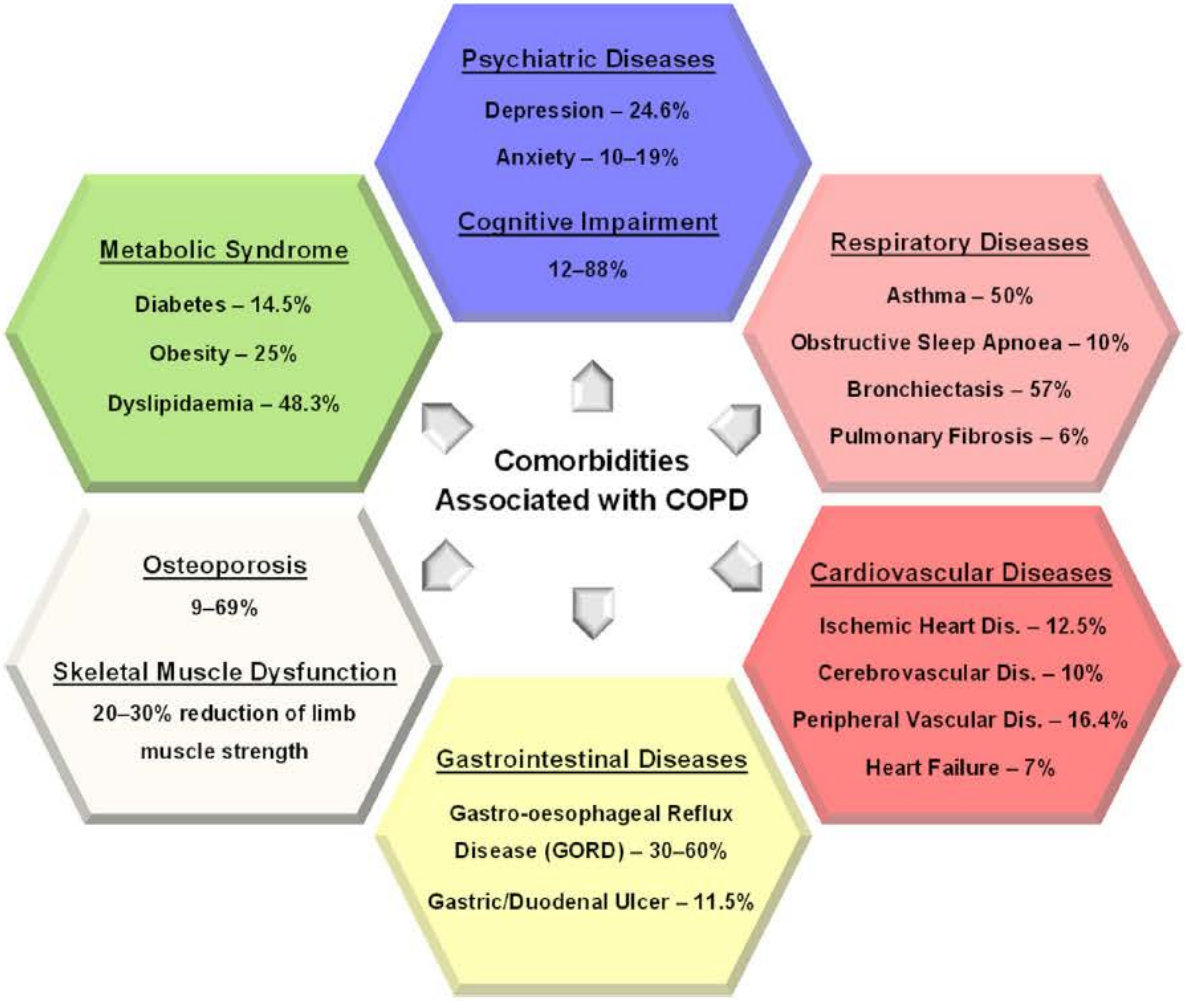
LiveWell™ Optimizing Chronic Disease Management

Patient Benefits and Outcomes

- **Improved exercise tolerance** (64 m in 6MWD)
- **Improved quality of life**
  - SGRQ reduced by 8.3 (52.9 to 44.6) at 3 months, 5.6 at 6 months, 5.3 at 1 year
- **Decreased healthcare utilization:**
  - COPD re-admissions reduced by 71%, hospital days by 62%, ER visits by 44% at 1 year
  - 3 year follow-up: COPD re-admissions reduced by 64%, hospital days by 29%, ER visits by 30%
- **Improved quality of life, enhanced exercise tolerance, reduced exacerbations and hospitalizations, and reduced healthcare costs ('cost-dominant').**

Saskatoon Health Region Annual Report, *LiveWell* COPD Chronic Disease Management Program, 2009

COPD Comorbidities and Conditions



Negewo NA, et al. *Respiratory Investigation* 2015; 53:249-258

Advanced COPD: Patients Want To Talk …

- about their diagnosis and disease process
- role of therapies in **improving symptoms and quality of life**
- their prognosis for survival and for quality of life
- **what dying might be like**
- advance care planning for future medical care and exacerbations
- **about what they don't want**

Curtis JR. *Eur Respir J* 2008; 32:796-803. Janssen DJ, et al. *Chest* 2011; 139:1081-1088

When Is A Patient Nearing EOL?

- Poor functional status (**MRC 5**)
- Severe acute **exacerbation(s)**
- **FEV_1** < 30-40% predicted
- Signs of **pulmonary hypertension**
- Respiratory failure with **CO_2 retention**
- **Body mass index** < 20 kg/m^2
- Patient is starting to **wish for or talk about death**
- *"Dying this year would not be a surprise"*

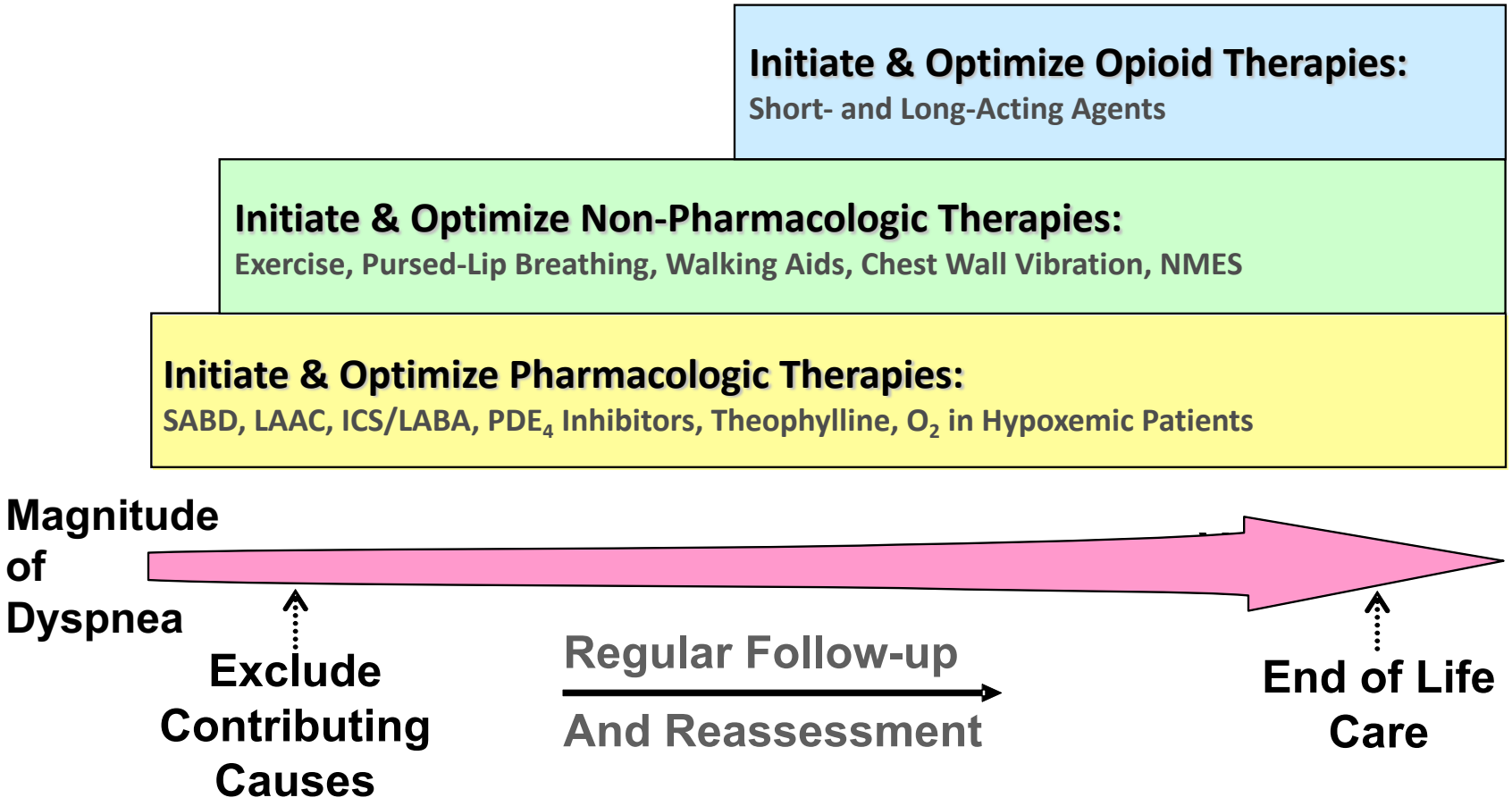
Goodridge DM, et al. *Can Resp J* 2009; 16:e51-e53. Curtis JR. *Eur Respir J* 2008; 32:796-803.

Guiding Principles

- frame discussion as an **integral part of care for all advanced COPD patients**
  - *'hope for the best and prepare for the worst'*
  - stress that discussing advance care planning will not diminish focus on maximizing the patient's survival
  - emphasize a **commitment to non-abandonment**
- inquire whether a **family member(s) should be present for the discussion**
- **discuss prognosis by referring to groups of people** rather than individuals
  - explicitly highlight uncertainty in prognostication
- **identify situations or health states the patient would consider 'worse than death'**

Curtis JR. *Eur Respir J* 2008; 32:796-803

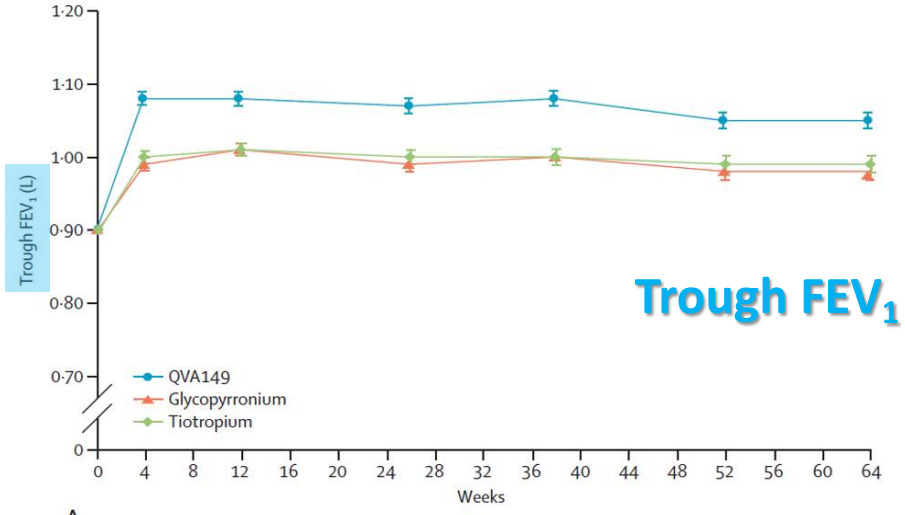
Comprehensive Approach to Management of Refractory Dyspnea in Advanced COPD



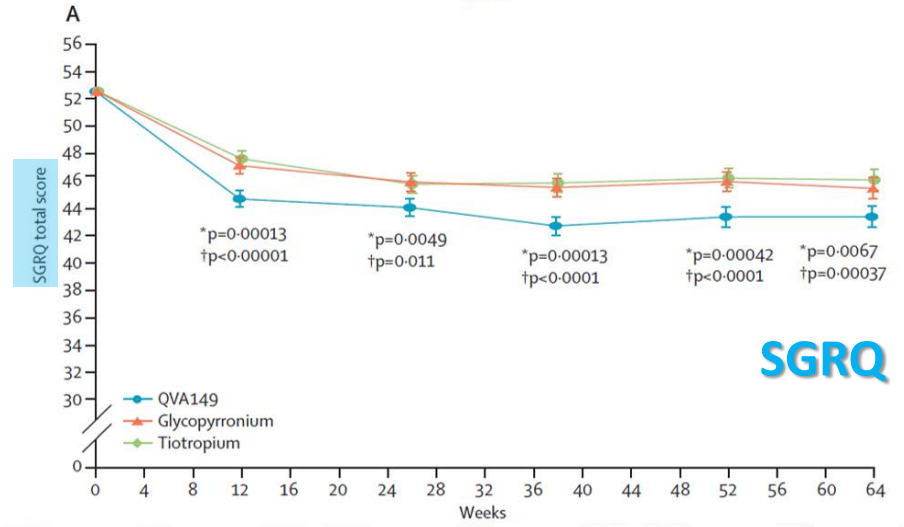
Marciniuk DD, *Can Resp J* 2011; 18:69-78

CANADIAN THORACIC SOCIETY

What About the Puffers?



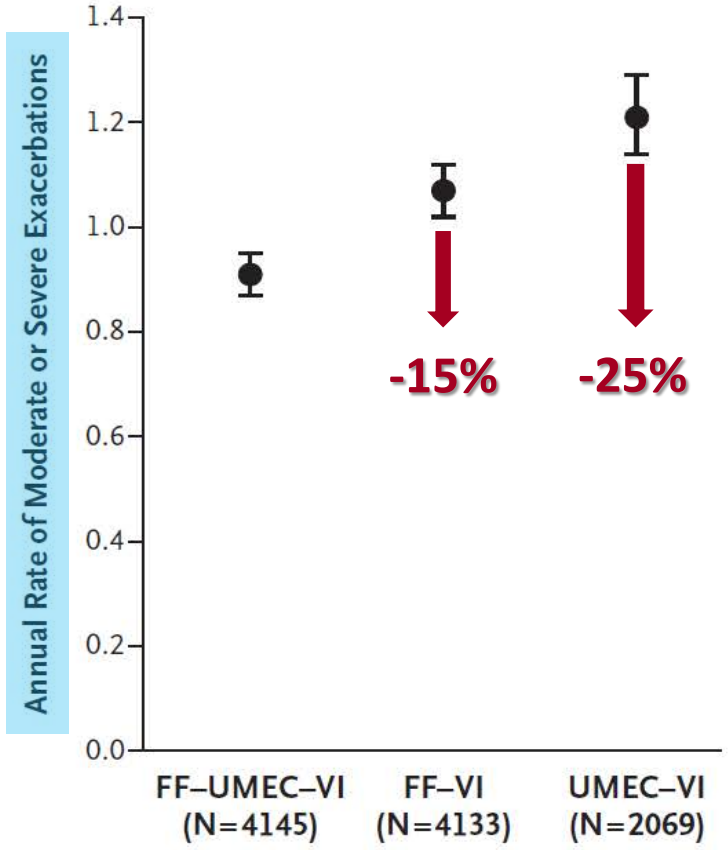
Trough FEV_1

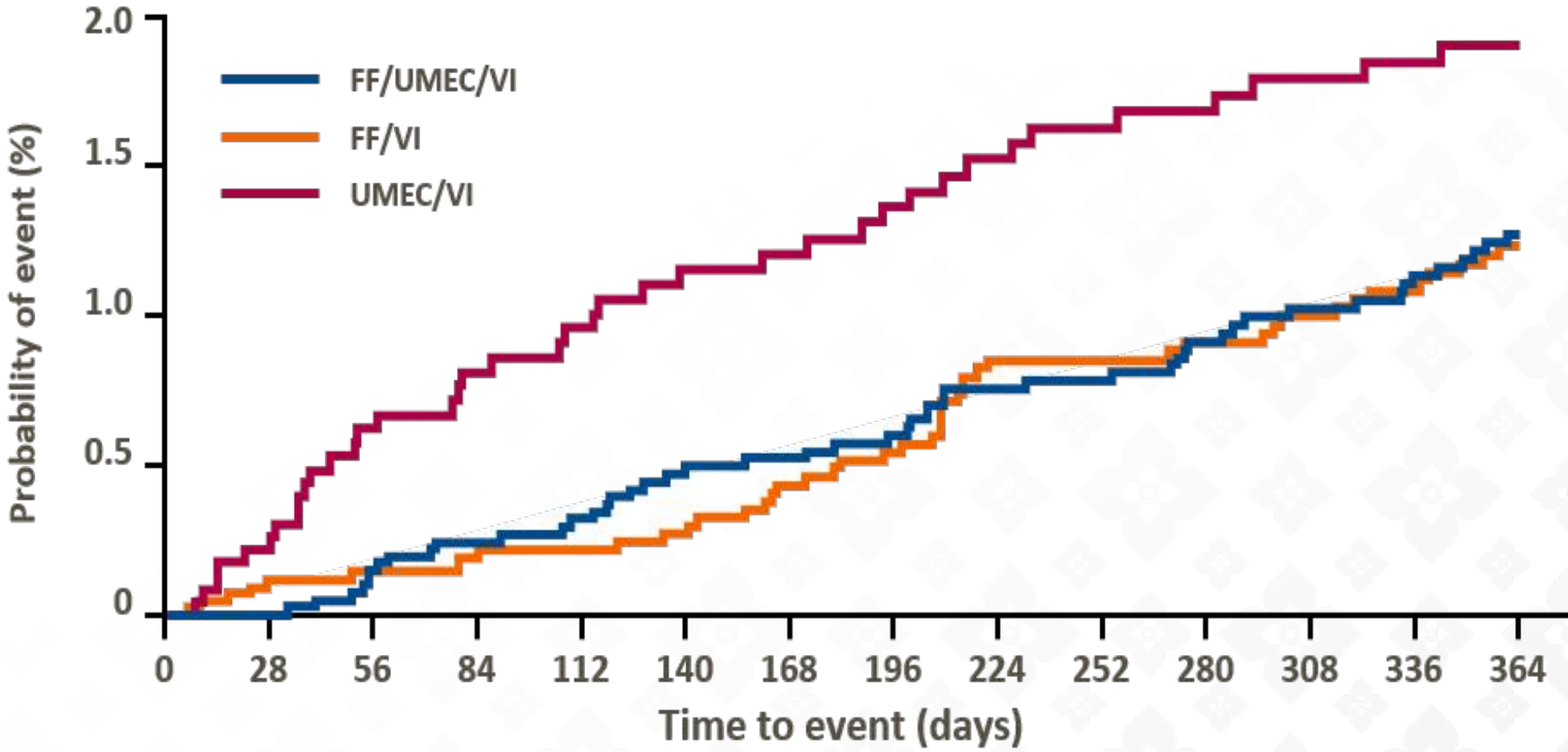


SGRQ

n=2224 subjects;
FEV_1 <50% predicted;
mean FEV_1 = 1.04 L
[37% predicted]

Wedzicha JA, et al. *Lancet Resp Med* 2013; 1(6):442





Rate of Moderate-Severe AECOPD

FF/UMEC/VI vs FF/VI [15% reduction, p<0.001]
vs UMEC/VI HR [25% reduction, p<0.001]

All-cause mortality significantly lower with ICS+ therapy

FF/VI vs UMEC/VI HR 0.61 [0.40-0.93, 39% reduction, p=0.022]
FF/UMEC/VI vs UMEC/VI HR 0.58 [0.38-0.88, 42% reduction, p=0.011]

Lipson DA, et al. *N Engl J Med* 2018; 378:1671-1680


CAUTION
THIS SIGN HAS
SHARP EDGES
DO NOT TOUCH THE EDGES OF THIS SIGN
ALSO, THE BRIDGE IS OUT AHEAD

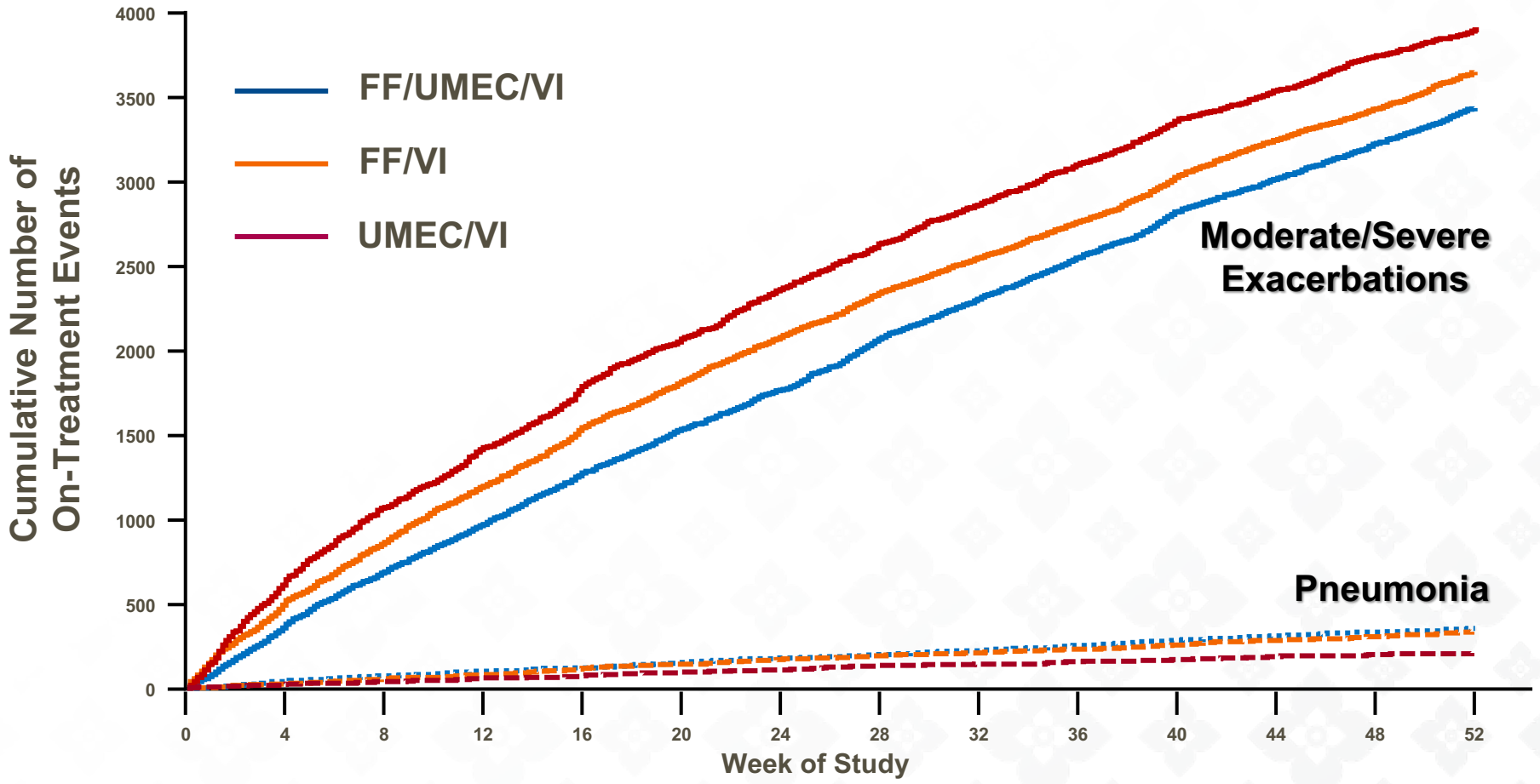
Distractions: 'Misguided' Concern ICS in COPD

ICS in COPD	Appendectomy
Increased risk of pneumonia 17-69% [1] (compared to no ICS)	**Increased risk of wound infection 130-925%** [2] (compared to no surgery)

- Absolute pneumonia risk increases to ~2.4%/yr [1]
- Even after accounting for this 'risk', there are **significant improvements in lung function, quality of life, dyspnea, activity, exercise performance, and AECOPD** with ICS use (as LABA/ICS) in COPD

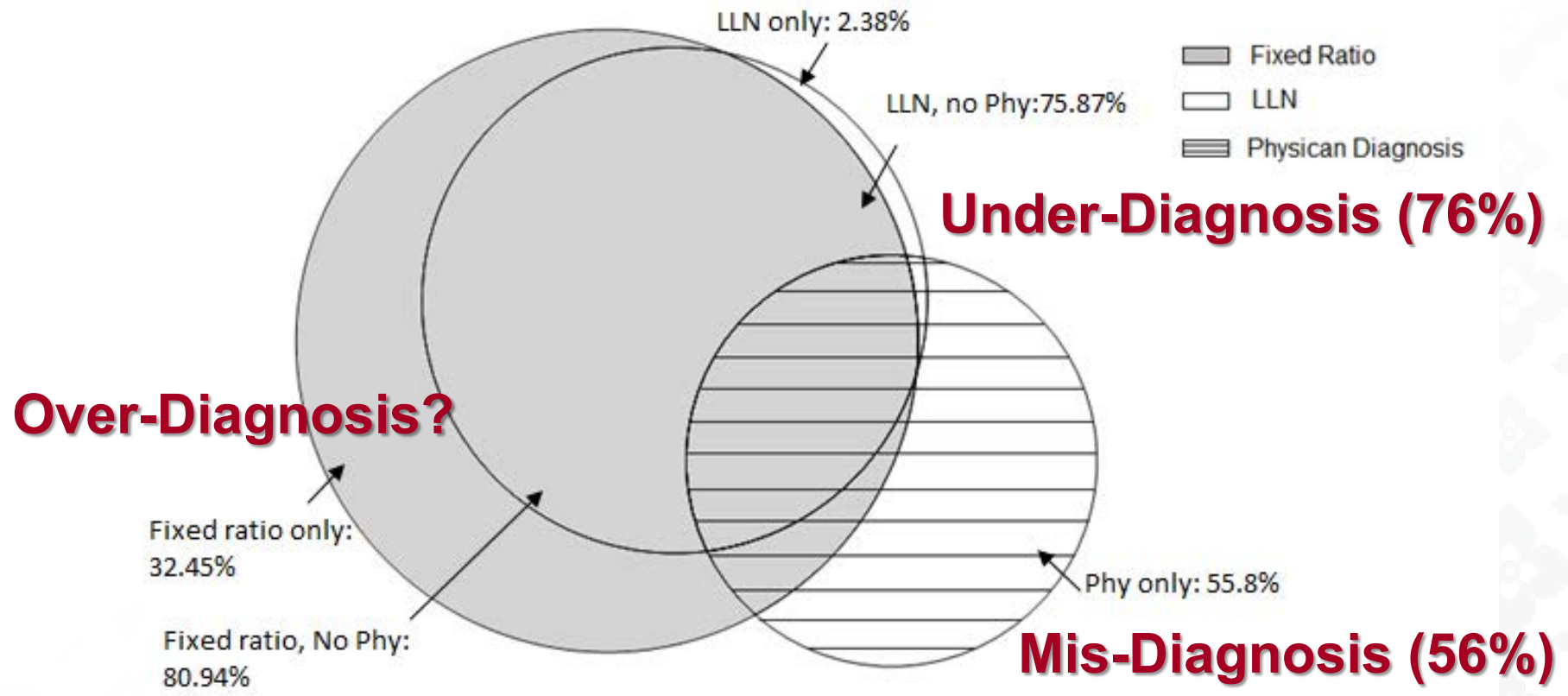
[1]Suissa S, et al. *Thorax* 2013:1029-1036. [2]Khan MN, et al. *JSLS* 2007; 11:363-367.

Moderate/Severe AECOPD vs Pneumonia

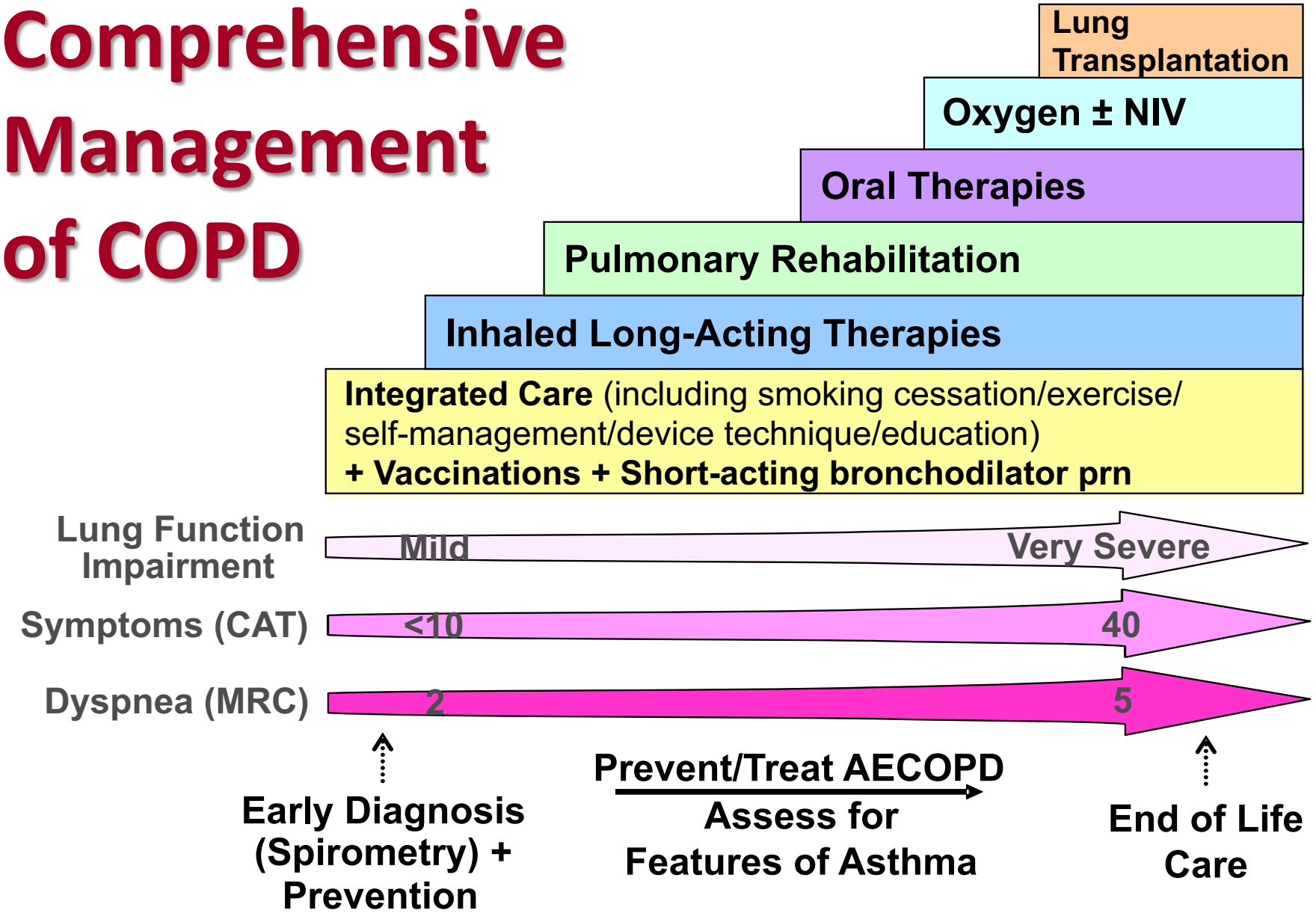


Lipson DA, et al. *N Engl J Med* 2018; 378:1671-1680, and ATS May 2018.

COPD [Under/Over/Mis]-Diagnosis ?



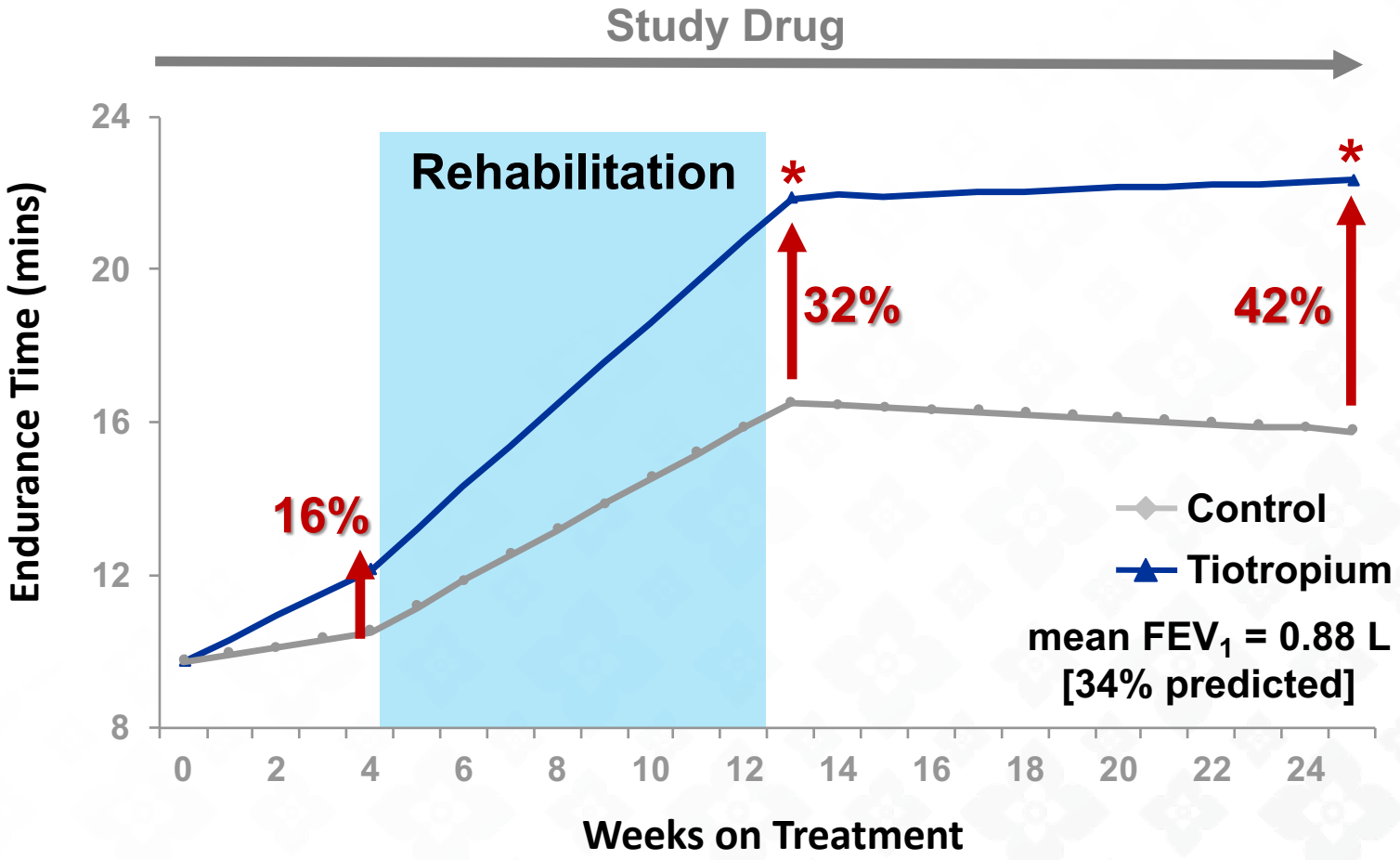
Comprehensive Management of COPD



Bourbeau J, et al. *Can J Resp Crit Care Med* 2017; 1(4):222-241

CANADIAN THORACIC SOCIETY

Bronchodilation and Pulmonary Rehabilitation



* = p<0.05

Casaburi R, et al. *Chest* 2005; 127:809-817

The Bottom Line …

- There are many **effective non-pharmacologic interventions and therapies** for the **management of COPD**
- Targeting **important clinical patient-centered endpoints for therapy and care** works best
- Utilizing **pharmacologic, non-pharmacologic and healthcare system interventions and strategies** together will improve the care and outcomes for patients suffering from COPD