COPD: Non-Pharmacologic Therapies

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COPD: Non-Pharmacologic Therapies

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

Research Funding (managed by University of Saskatchewan)
AstraZeneca, Boehringer Ingelheim, Canada Health Infoway, Canadian Institute of Health Research, GlaxoSmithKline, Lung Association of Saskatchewan, Lung Health Institute of Canada, Novartis, Sanofi, Saskatchewan Health Research Foundation, Schering-Plough

Employee
University of Saskatchewan
COPD: Non-Pharmacologic Therapies
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• 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 ...
COPD: Non-Pharmacologic Therapies

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 $\geq$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**

COPD: Non-Pharmacologic Therapies

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

Comprehensive COPD Management

- Admissions for other reasons: -57%
- Admissions for exacerbations: -40%
- Admissions the year before the study: +4%

- Non-scheduled visits: -59%
- Emergencies for other diseases: -23%
- Emergency for exacerbations: -41%
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 Leitnerman, MS; Soe Soe Thwin, MD, PhD, MS; Grant D. Huang, PhD, MPH; Richard Robbins, MD; Perumvella S. Sriman, MD; Amir Sharifkhani, MD; M. Jeffrey Mador, MD; George Sarosi, MD; Ralph J. Panos, MD; Padmeshri Rastege, MD; Todd H. Wagner, PhD; Steven A. Mazucca, PhD; Colleen Shannon, MPH; Cindy Colling, RPH, MS; Matthew H. Liang, MD, MPH; James K. Stoller, MD, MS; Louis Fiere, MD, MPH; and Dennis E. Niewold, 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: NCT00395683)

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 19 in the usual care group (hazard ratio, 1.30 [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 = 0.085).

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.
**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

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 practice 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
Chronic Disease Management Program

For more information about the CDM Program, please contact:
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live-well@saskatoonhealthregion.ca
<table>
<thead>
<tr>
<th>Group Exercise and Rehabilitation</th>
<th>Disease-Specific Management</th>
<th>Patient Self-Management</th>
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</thead>
<tbody>
<tr>
<td>• Community-based exercise and rehabilitation programming</td>
<td>• Inter-professional team working with the patient, family, and Family Physician</td>
<td>• Individualized plan of action</td>
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<tr>
<td>• Group education</td>
<td>• Evidence-based optimal care delivery</td>
<td>• Patient-led group support “LiveWell with Chronic Conditions”</td>
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<tr>
<td>• Group and social support</td>
<td></td>
<td>• Enhanced self-management skills</td>
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**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

Psychiatric Diseases
- Depression – 24.6%
- Anxiety – 10–19%

Cognitive Impairment
- 12–88%

Metabolic Syndrome
- Diabetes – 14.5%
- Obesity – 25%
- Dyslipidaemia – 48.3%

Respiratory Diseases
- Asthma – 50%
- Obstructive Sleep Apnoea – 10%
- Bronchiectasis – 57%
- Pulmonary Fibrosis – 6%

Cardiovascular Diseases
- Ischemic Heart Dis. – 12.5%
- Cerebrovascular Dis. – 10%
- Peripheral Vascular Dis. – 16.4%
- Heart Failure – 7%

Gastrointestinal Diseases
- Gastro-oesophageal Reflux Disease (GORD) – 30–60%
- Gastric/Duodenal Ulcer – 11.5%

Osteoporosis
- 9–69%

Skeletal Muscle Dysfunction
- 20–30% reduction of limb muscle strength

Comorbidities Associated with COPD

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

When Is A Patient Nearing EOL?

- Poor functional status (MRC 5)
- Severe acute exacerbation(s)
- $\text{FEV}_1 < 30\text{-}40\%$ predicted
- Signs of pulmonary hypertension
- Respiratory failure with $\text{CO}_2$ retention
- Body mass index $< 20 \text{ kg/m}^2$
- Patient is starting to wish for or talk about death
- “Dying this year would not be a surprise”

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

Initiate & Optimize Pharmacologic Therapies:
- SABD, LAAC, ICS/LABA, PDE$_4$ Inhibitors, Theophylline, O$_2$ in Hypoxemic Patients

Initiate & Optimize Non-Pharmacologic Therapies:
- Exercise, Pursed-Lip Breathing, Walking Aids, Chest Wall Vibration, NMES

Initiate & Optimize Opioid Therapies:
- Short- and Long-Acting Agents

Magnitude of Dyspnea

Exclude Contributing Causes

Regular Follow-up And Reassessment

End of Life Care

Marciniuk DD, Can Resp J 2011; 18:69-78
What About the Puffers?

n=2224 subjects;
FEV$_1$ <50% predicted;
mean FEV$_1$ = 1.04 L
[37% predicted]

**COPD: Non-Pharmacologic Therapies**

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]

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**
- Increased risk of pneumonia
  - 17-69% \(^1\)
  - (compared to no ICS)

**Appendectomy**
- 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

COPD: Non-Pharmacologic Therapies

Moderate/Severe AECOPD vs Pneumonia

COPD: Non-Pharmacologic Therapies

COPD [Under/Over/Mis]-Diagnosis?

Under-Diagnosis (76%)

Over-Diagnosis?

Mis-Diagnosis (56%)

Under-Diagnosis? (81%)
Comprehensive Management of COPD

- Oxygen ± NIV
- Oral Therapies
- Pulmonary Rehabilitation
- Inhaled Long-Acting Therapies
- Integrated Care (including smoking cessation/exercise/self-management/device technique/education) + Vaccinations + Short-acting bronchodilator prn

Lung Function Impairment
- Mild
- Very Severe

Symptoms (CAT)
- <10
- 40

Dyspnea (MRC)
- 2
- 5

Early Diagnosis (Spirometry) + Prevention

Prevent/Treat AECOPD

Assess for Features of Asthma

End of Life Care

Bronchodilation and Pulmonary Rehabilitation

Study Drug

<table>
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<tr>
<th>Weeks on Treatment</th>
<th>Endurance Time (mins)</th>
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<tbody>
<tr>
<td>0</td>
<td>Control</td>
</tr>
<tr>
<td>12</td>
<td>Tiotropium</td>
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- **Control**
  - mean FEV₁ = 0.88 L
  - [34% predicted]

- **Tiotropium**
  - 16% increase by 4 weeks
  - 32% increase by 12 weeks
  - 42% increase by 24 weeks

* = p<0.05

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.