Impact of a pharmacist-driven steroid step-down protocol for the treatment of acute exacerbations of COPD in hospitalized patients

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Presentation Objective
To describe the impact of a pharmacist-driven steroid step-down protocol in hospitalized patients treated for AECOPD

Steroid Use in AECOPD
- Numerous meta-analyses have demonstrated lower doses and shorter courses of therapy are just as effective as higher doses and longer courses.
  
- Advantages of oral therapy
  - Reduced length of stay
  - Convenience for patient and hospital personnel
  - Less costly
  - Decreased risk of infection

- In an effort to decrease the use of high-dose steroids at our facility, a pharmacist-driven steroid step-down protocol was implemented

Disclosure Statement
These individuals do not have anything to disclose concerning possible financial or personal relationships with commercial entities (or their competitors) that may be seen as relevant to this presentation.

PRIMARY INVESTIGATOR
- Melissa Johnson, Pharm.D.

CO-INVESTIGATORS
- Doug Brown, Pharm.D., BCPS
- Sean Ustic, Pharm.D., BCCCP
- Mercy Niran, Pharm.D.
- Tatiana Hernandez, Pharm.D., BCCPS

Background
- In 2008, 514,000 hospitalizations in the U.S. were due to AECOPD
- Administration of systemic corticosteroids has been a mainstay of treatment for AECOPD
- Common practice utilizes high-dose intravenous steroids or a tapered course of IV steroids
  - GOLD guidelines recommends using 40 mg oral prednisone per day for five days

Pharmacist-Driven Steroid Step-Down Protocol

<table>
<thead>
<tr>
<th>INCLUSION CRITERIA</th>
<th>EXCLUSION CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admission for AECOPD</td>
<td>Continuous BiPAP, CPAP, or HFNC</td>
</tr>
<tr>
<td>Received IV corticosteroids ≥ 24 hrs.</td>
<td>Mechanically ventilated</td>
</tr>
<tr>
<td>Ability to take oral medications</td>
<td>Acute respiratory failure (life-threatening)</td>
</tr>
<tr>
<td>Maintaining O2 saturations &gt; 90% on ≤ 5 L/min of supplemental oxygen</td>
<td>Hypersensitivity to prednisone</td>
</tr>
<tr>
<td>Pulmonary team consulted for COPD management</td>
<td>Requiring steroids for conditions other than AECOPD</td>
</tr>
</tbody>
</table>

BiPAP: bilevel positive airway pressure; CPAP: continuous positive airway pressure; HFNC: high-flow nasal cannula
Pharmacist Steroid Step-Down Protocol

Patient identified for potential steroid step-down
Pharmacist chart review
Communication with nursing staff to assess oxygen requirements and mental status
Discontinue current IV steroid order
Order prednisone 40mg PO once daily x 5 days
Intervention documented. Continued clinical monitoring

Study Purpose
To evaluate clinical outcomes of a pharmacist-driven steroid step-down protocol

Research Setting
South Florida Baptist Hospital
- 147-bed acute care, community hospital
- Part of BayCare Health System’s 15 hospital network

Study Population
INCLUSION CRITERIA
- Patients hospitalized for AECOPD
- Use of steroid therapy for AECOPD
- Pulmonology consulted

EXCLUSION CRITERIA
- Patients requiring steroids for conditions other AECOPD
- Patients < 18 years of age

Treatment Groups
CONVENTIONAL GROUP
- Patients who received IV corticosteroids for the treatment of AECOPD without pharmacist intervention

PROTOCOL GROUP
- Patients switched to oral prednisone 40 mg daily for 5 days by pharmacist-driven steroid step-down protocol for the treatment of AECOPD
Study Endpoints

**PRIMARY OUTCOME**
- 30-day hospital readmission with primary diagnosis of AECOPD

**SECONDARY OUTCOMES**
- Cumulative dose of prednisone equivalents
- Duration of inpatient steroid therapy
- Time to steroid step-down
- Glycemic control
- 30-day ED visits
- Length of stay

Power Calculation
- Baseline 30-day readmission rate of 14.57%
- Non-inferiority margin of 5%
- Pilot sample size (n=53): 13.2% 30-day readmission rate
- Power: 80%
- Alpha: 0.05
- Total of 364 subjects in each group

Statistical Analysis
- All statistical data: Minitab 18.1 software
- Baseline characteristics: Descriptive statistics
- Discrete data: Chi-squared test
- Continuous data
  - Parametric: 2-Sample t-test
  - Nonparametric: Mann-Whitney U test

Subject Selection
- 240 patients identified for conventional therapy
- 124 patients randomly selected for inclusion to match sample size of protocol therapy
- 130 patients identified for protocol therapy
- 6 excluded: did not receive prednisone as an inpatient
- 124 patients included

Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Conventional (n=124)</th>
<th>Protocol (n=124)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>67 (11)</td>
<td>67 (11)</td>
<td>0.886</td>
</tr>
<tr>
<td>Males, n (%)</td>
<td>41 (41)</td>
<td>41 (41)</td>
<td>1</td>
</tr>
<tr>
<td>History of DM, n (%)</td>
<td>46 (37)</td>
<td>21 (17)</td>
<td>0.003</td>
</tr>
<tr>
<td>Mean A1c of DM patients, %</td>
<td>7.9</td>
<td>7.4</td>
<td>0.435</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Smoking Status, n (%)</th>
<th>Current</th>
<th>Past</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room air</td>
<td>32 (26)</td>
<td>32 (27)</td>
<td>32 (26)</td>
</tr>
<tr>
<td>Nasal cannula/OxyMask</td>
<td>74 (60)</td>
<td>76 (64)</td>
<td>74 (60)</td>
</tr>
<tr>
<td>BIPAP/HFNC/Intubated</td>
<td>18 (14)</td>
<td>12 (10)</td>
<td>14 (11)</td>
</tr>
</tbody>
</table>

Primary Outcome Results

<table>
<thead>
<tr>
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<th>Conventional (n=124)</th>
<th>Protocol (n=124)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-day readmission with primary diagnosis of AECOPD, n (%)</td>
<td>21 (16.9)</td>
<td>14 (11.3)</td>
<td>0.016</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Difference in 30-Day Readmission Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>-15%</td>
</tr>
<tr>
<td>-10%</td>
</tr>
<tr>
<td>-5%</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>5%</td>
</tr>
<tr>
<td>10%</td>
</tr>
<tr>
<td>15%</td>
</tr>
</tbody>
</table>

*Mean ± SD

**Abbreviations:**
- DM: diabetes mellitus
- AECOPD: Acute Exacerbation of Chronic Obstructive Pulmonary Disease
- O2: Oxygen
- HFNC: High Flow Nasal Cannula
Secondary Outcome Results

<table>
<thead>
<tr>
<th></th>
<th>Conventional (n=124)</th>
<th>Protocol (n=124)</th>
<th>Comparison Measure (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean cumulative dose of prednisone equivalents, mg</td>
<td>399</td>
<td>216</td>
<td>183 (118, 248)</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean duration on steroid therapy while inpatient, days</td>
<td>3.8</td>
<td>2.5</td>
<td>1.3 (0.9, 1.8)</td>
<td>0.001</td>
</tr>
<tr>
<td>Inpatient transition to oral steroid Yes, n (%)</td>
<td>38 (31)</td>
<td>124 (100)</td>
<td>2.3 (1.3, 3.3)</td>
<td>0.000</td>
</tr>
<tr>
<td>Mean time from admission, days</td>
<td>4.7</td>
<td>2.4</td>
<td>0.96 (0.3, 1.6)</td>
<td>0.056</td>
</tr>
</tbody>
</table>

Secondary Outcome Results Cont.

<table>
<thead>
<tr>
<th></th>
<th>Conventional (n=124)</th>
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<th>Comparison Measure (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean blood glucose while on steroid therapy, mg/dL</td>
<td>186</td>
<td>183</td>
<td>3.0 (-15.4, 21.4)</td>
<td>0.748</td>
</tr>
<tr>
<td>Glycemic control* while on steroid therapy, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>56.5</td>
<td>58.4</td>
<td>-1.9 (-13.4, 9.6)</td>
<td>0.748</td>
</tr>
<tr>
<td>DM patients</td>
<td>38.5</td>
<td>33.5</td>
<td>-5.0 (-19.4, 9.4)</td>
<td>0.491</td>
</tr>
<tr>
<td>Non-DM patients</td>
<td>78.6</td>
<td>71.2</td>
<td>-7.4 (-21.1, 6.3)</td>
<td>0.288</td>
</tr>
<tr>
<td>Mean length of stay, days</td>
<td>3.6</td>
<td>3.2</td>
<td>0.24 (-0.3, 0.8)</td>
<td>0.405</td>
</tr>
<tr>
<td>ED visits within 30 days of index visit with AECOPD, n (%)</td>
<td>23 (18.6)</td>
<td>19 (15.3)</td>
<td>3.2 (-6.1, 12.6)</td>
<td>0.498</td>
</tr>
</tbody>
</table>

*Capillary blood glucose levels between 70-180 mg/dL

Conclusion

- Pharmacist-driven steroid step-down protocol was non-inferior to conventional therapy
  - Supports the use of a pharmacist steroid step-down protocol for hospitalized patients treated for AECOPD
- Pharmacist-driven steroid step-down protocol led to:
  - Decreased inpatient steroid doses and duration
  - No difference in glycemic control, ED visits or length of stay

Strengths

- Homogenous groups for baseline characteristics
- Single pulmonary group
- Adequately powered for the primary outcome

Limitations

- Retrospective design
- Single-center
- Multiple physician groups managing glucose
- Unmeasured confounders

Contributions to Practice

- This study validates current literature and guideline recommendations for using low-dose steroids for shorter durations for the treatment of AECOPD
- Positively changed physician prescribing patterns at our facility
  - Physicians began taking the initiative to deescalate steroid therapy without pharmacist intervention
- Protocol will be further analyzed for potential system-wide implementation
Self Assessment

Which of the following are advantages for using oral steroid therapy compared to intravenous steroid therapy for acute exacerbations of COPD?

a. Decreased utilization of steroids
b. Improved glycemic control
c. Reduced 30-day ED visits
d. All of the above

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