Critically Appraised Topic: Efficacy of PO vs IV Steroids in the Treatment of Severe COPD Exacerbation

Question: Even though it is important to hospitalize patients with a severe exacerbation of COPD due to concerns of impending respiratory failure, is it necessary to treat with IV steroids due to the bioavailability of oral steroids?


Study Description: This was a single center prospective, randomized, double-blind, double-dummy, placebo-controlled, parallel-group clinical study with treatment failure as the primary outcome. The study was devised to determine if oral administration of prednisolone was inferior to IV administration of prednisolone in the treatment of patients hospitalized for an exacerbation of COPD.

Study Relevance: Though systemic corticosteroids have been shown to be beneficial in the treatment of COPD exacerbations, no study has shown the optimal route of administration. Preferred route of administration varies between hospitals and individual physicians. Oral administration yields fewer nosocomial complications and is overall cheaper.

Research Question:
- Population: 435 individuals with a total of 581 exacerbations were referred to Isala klinieken hospital for COPD exacerbation. A total of 210 patients were eligible for the study. 107 were randomized to receive IV prednisolone and 103 were randomized to received oral prednisolone.
  - Inclusion criteria: age>40, >10 pack-year hx of smoking, stage II COPD
- Intervention/Control: Patients received either a 5-day course of IV or oral prednisolone (60 mg) together with a placebo medication. After 5 days, all patients received oral prednisolone in a dosage of 30 mg once daily and subsequently tapered by 5 mg to 0 mg or a prior maintenance dosage. All patients received nebulized ipratropium/albuterol and Augmentin (or doxycycline if PCN allergic).
- Outcome: Treatment failure within 90 days was similar when comparing IV and oral prednisolone.

Validity:
- Did the experimental and control groups start out with a similar prognosis? Yes. Pts that meet inclusion criteria were randomized to either the IV or oral group.
- Was randomization concealed? Yes.
- Were patients analyzed in the groups to which they were randomized? Yes.
- Were groups similar regarding known prognostic factors? Yes.
- Did the experimental and control groups retain a similar prognosis after the study started? Yes
- Were patients, clinicians, and outcome assessors aware of group allocation? No. Pt were given placebo of either IV or oral medications which were similar in appearance to the prednisolone.
- Was follow-up complete? Yes. The follow-up period was 90 days with outpatient visits at 42 and 90 days. If follow-up visits were missed, data was obtained from the patient’s general practitioner to prevent failure rates due to missing data.

Summary of Results:
- No difference in failure rates between IV (61.7%) and oral (56.3%) prednisolone.
- No difference in rate of early or late treatment failure.
  - Early: IV (17.8%) vs oral (18.4%)
  - Late: IV (54%) vs oral (47%)
- Reasons for Treatment Failure: Table 2
- No difference in mean FEV1 improvement or improvement in health-related quality of life.

Conclusion: Therapy with oral prednisolone is as effective as IV treatment in the first 90 days after treatment of a COPD exacerbation. It should be the preferred route if patients can tolerate oral intake.