



ORAL CORTICOSTEROIDS TAPERING PROTOCOL FOR SEVERE ASTHMA



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INTRODUCTION

Systemic corticosteroids are commonly used for the management of severe asthma, either episodically for exacerbations, or chronically as maintenance therapy in patients with poor response to inhaled therapies. However, chronic use of corticosteroids can lead to systemic side effects to the patients, such as osteoporosis, cardiovascular complications, diabetes, and obesity. It also poses a risk of inhibiting the adrenal glands' production of cortisol (also known as “adrenal insufficiency”). The risk of developing side effects with systemic corticosteroids increases with cumulative dose over time.

New biologic treatments in severe asthma have emerged in recent years. These treatments have shown to be able to improve clinical outcomes, and at the same time, reduce the need for oral corticosteroids. With the use of biologics, the patients are able to reduce, and in most cases, eliminate oral corticosteroids completely. The study protocol from one of the OCS reduction studies, the PONENTE Study with the use of benralizumab in specific, provides an evidence-based guidance for individualized tapering and complete elimination of oral corticosteroids among severe asthma patients.

The purpose of this protocol is to provide healthcare professionals a guidance on how to safely down-titrate oral corticosteroids doses in patients with severe asthma who is currently on chronic OCS therapy, and started on biologic treatment, following improvements of symptoms of asthma.

Figure 1: Flow Chart to Taper Off OCS Doses

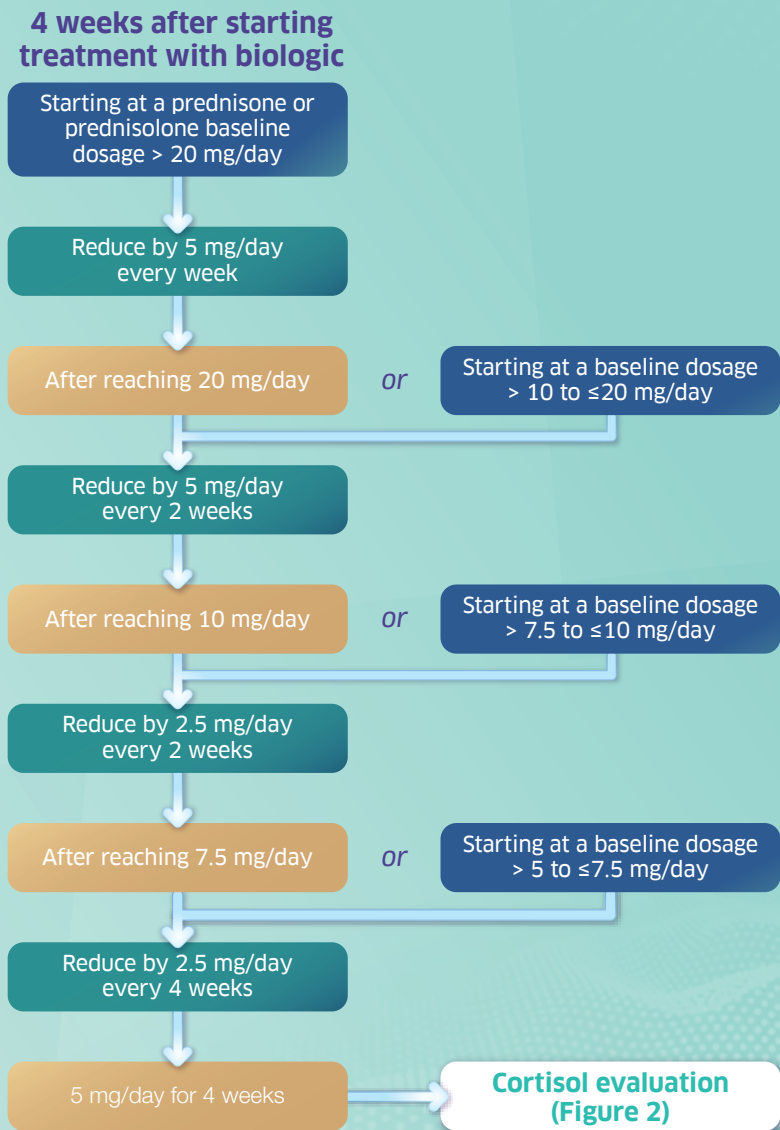
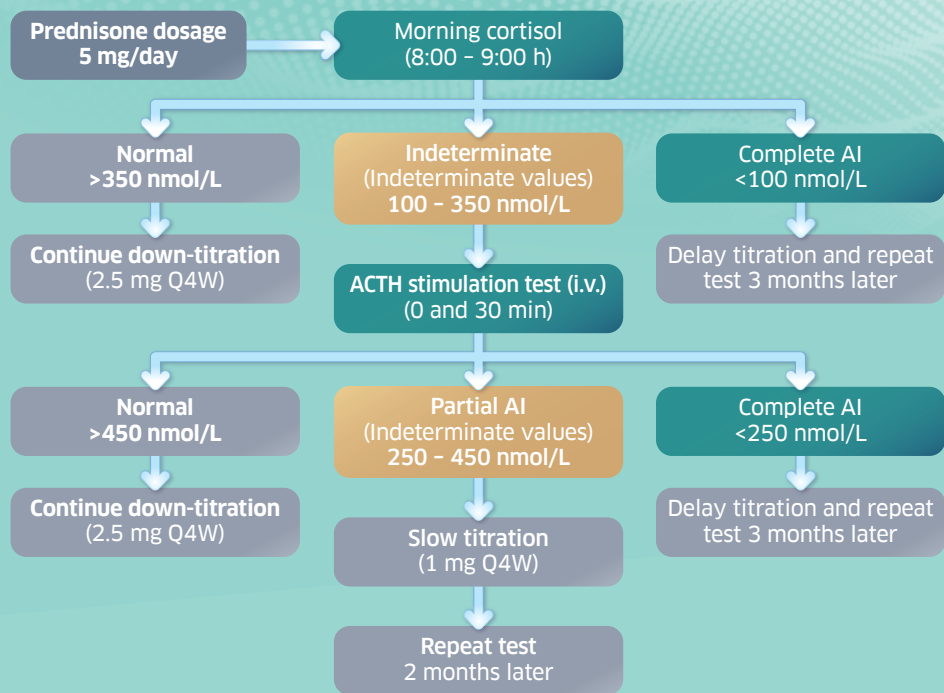


Figure 2: Cortisol When Reaching A Prednisone Dose = 5 mg/day



* Do ensure to double check the units used in the laboratory.

This OCS tapering algorithm was adapted based on the published PONENTE study with the use of benralizumab. Further clinical evidence and assessment may be required to facilitate implementation of this algorithm with other biologics.

If there are signs / symptoms of AI, physicians should reduce OCS more slowly (1 mg/Q4W), regardless of cortisol concentrations

PRACTICAL ADVICE

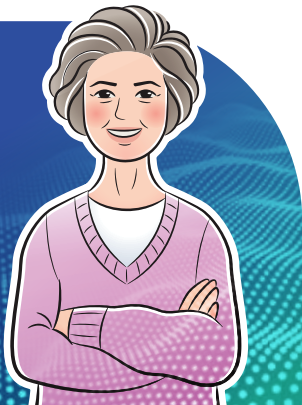
- 1 Follow up on asthma control at each tapering of oral corticosteroids
- 2 Keep the prescribed inhaled medications
- 3 Check the local laboratory's reference value for S-cortisol
- 4 During the Synacthen test (also known as ACTH stimulation test), take the sample / conduct the test before taking glucocorticoid medication (including inhaled steroids) that morning
- 5 In a case of a suspected adrenal insufficiency (such as nausea, abdominal pain, weight loss, orthostatism), check ACTH and consult an endocrinologist if necessary

PATIENT CASE

Female, 58, housewife

Adult onset of asthma (age 24) with progressive severity and sinusitis without polyps, never smoked, limited activity due to asthma.

5-6 exacerbations and 1-2 hospital admissions per year. Referred with suspected OCS-related complications, including dull constant headaches and hip pain.



ACT: 4 – 15 (at best)

Current maintenance medication:

High-dose ICS / LABA, LAMA, LTRA, OCS-dependent, 12 – 15 mg/day on average for the last 4 years. Good to optimal inhaler technique.

Acute OCS use:

Four short courses of OCS per year (40 mg/day for 7 days) plus 5 – 6 bursts of injectable depot steroids.

Asthma-related comorbidities:

Sinusitis

OCS-related comorbidities:

Skin bruising, weight gain, Cushingoid appearance, hypertension, Type II diabetes, cataracts, osteoporosis

Physical examination	Obese (BMI 32), bruising on skin, blood pressure 145 - 95 mm, bilateral cataracts
Nasal disease	Chronic rhinosinusitis
Spirometry / peak flow	Severe obstruction FEV1: 1100 mL/s (45% predicted) with 230 mL reversibility after salbutamol
Allergy testing	Induction of sputum caused severe exacerbation samples showed 5% eosinophils, allergy testing positive to dust mites
Blood tests, including biomarkers	Eosinophils 320 cells/ μ L, FeNO 35 ppb, IgE 185 IU/mL, glucose 145 mg/mL. ALT 64 U/L, AST 72 U/L
Imaging (chest X-ray or lung CT scan)	Vertebral wedging of T11 Liver ultrasound suggested fatty liver

Diagnosis:

Adult onset of severe, eosinophilic asthma

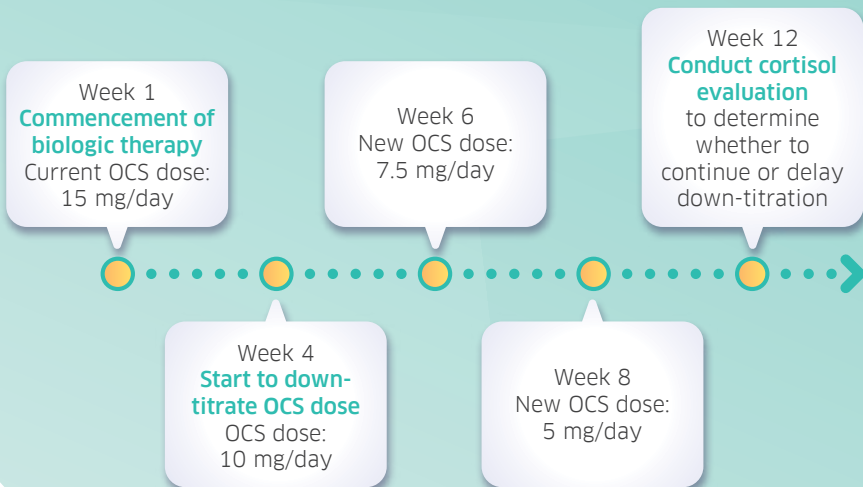
Related comorbidities:

Obesity, chronic rhinosinusitis, fatty liver, hypertension, cataracts, skin bruising and osteoporosis

Treatment / management plan:

Patient is considered a candidate for biological treatment targeting eosinophils as a steroid-sparing strategy

Strategy to step down OCS dose was planned following the start of biological therapy



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