

DSEN ABSTRACT

Hair cortisol as a novel biomarker of HPA suppression by inhaled corticosteroids (ICS) in children & pregnant patients with asthma

Summary

- This project was conducted to assess ICS use in children and pregnant women to determine safety concerns related to ICS use in children (especially the very young) and during pregnancy.

Key messages

- This study has shown it is feasible to measure cortisol over time in human hair. Of particular importance is that hair cortisol concentrations did not differ based on the ICS drug or dose used.

Authors: Bruce Carleton and the DSEN-SEARCH Team

For more information, please contact Dr. Bruce Carleton:
bcarleton@popi.ubc.ca

What is the issue?

- Recently, questions have been raised concerning systemic adverse effects of long-term ICS use. These concerns are particularly important with respect to ICS use in children and during pregnancy due to the limited number of existing studies focusing on these populations where the drugs may be used for long periods of time (children) or during periods of particular vulnerability (pregnancy, fetal risk). By comparing the safety profiles of the 5 ICS drugs currently approved for use in Canada (beclomethasone, budesonide, ciclesonide, fluticasone and mometasone) we will be able to provide recommendations on the optimal choice of ICS drugs in these patient populations.

What was the aim of the study?

- To identify differences in safety profiles between inhaled corticosteroids (ICS) when used in children and during pregnancy by evaluating the incidence of ICS-induced adverse effects, for example, by measuring hair cortisol concentrations as a biomarker of adrenal suppression, and to determine the effect of clinical factors on the safety of ICS.

How was the study conducted?

- In collaboration with the Canadian Pharmacogenomics Network for Drug Safety (CPNDS), children and pregnant women who have been treated with ICE were enrolled from surveillance sites across Canada (Vancouver, Winnipeg and Toronto).
- Clinical data and hair samples were collected and hair cortisol concentrations were measured using enzyme immunoassay.
- Analyses were conducted to identify associations between the ICS characteristics (type, dose, and pattern of use) and participant clinical factors compared with hair cortisol concentrations as a biomarker of adrenal suppression and incidence of adverse drug reactions associated with ICS use to assess the overall safety of each ICS.

What did the study find?

- Hair cortisol concentrations (HCC) were compared among children with and without asthma. 5.6% of children using inhaled corticosteroids (ICS) had very low HCC, indicative of chronically low cortisol compared to none in the control group. HCC may be a biomarker for determining chronic adrenal suppression due to ICS use in children.
- HCC most significantly increased with age, body mass index, sex, and significantly decreased with intranasal corticosteroid use.
- HCC did not differ based on the specific ICS drug or the dose used.
- Study in pregnant women showed that HCC increased over the course of pregnancy for all women but the increase was significantly dampened in women with asthma.
- Women with asthma who used ICS ≥ 5 doses per week had significantly lower HCC in the third trimester than healthy controls.

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Link to publications: [Smy et al, 2015](#); [Smy et al, 2016](#); [Smy et al, 2018](#).