

Health Care Practitioner Knowledge About Dosing And Side Effects Of Fluticasone Propionate Metered-Dose-Inhaler For Children With Asthma

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Abstract

RATIONALE: A 6 year-old child developed Cushing's Syndrome after 16 months of treatment with an FDA-unapproved dose (110mcg) of the inhaled corticosteroid (ICS) fluticasone propionate metered-dose-inhaler (FP-MDI) for asthma. The objective was to assess health care practitioner (HCP) knowledge about FP-MDI dosing and side effects. **METHODS:** Anonymous and interactive polling was conducted using TurningPoint software and hand-held devices before and after PowerPoint presentation of the case during live meetings of HCPs across the United States. During the presentation, education about FDA-approved FP-MDI doses and side effects was provided. **RESULTS:** Presentations (n=40) were delivered to 790 HCPs, including asthma specialists. Before the presentation, only 26% of HCPs knew the dose of FP-MDI that is FDA-approved for children <12 years of age (44mcg only), and only 28% were confident in their ability to detect and diagnose growth and adrenal suppression secondary to ICS in a child with asthma. After the presentation, the respective values were 97% and 89% (p<0.05). FP-MDI was the ICS with which 43% were most experienced, yet only 11% knew the Asthma Guideline-recommended medium dose of FP-MDI for 5-11 year old children (>176-352mcg daily). A high percentage (49%) indicated that between 21% and 80% of 5-11 year old children that they treat with FP-MDI receive the 110mcg dose. **CONCLUSIONS:** HCPs are deficient in knowledge about FDA-approved FP-MDI doses and side effects and use FDA-unapproved doses, placing children at risk for developing serious systemic side effects. The reasons are unclear, but better methods to educate HCPs about ICS dosing and side effects are needed.

Introduction

A 6 year-old child developed Cushing's Syndrome after 16 months of treatment with an FDA-unapproved dose (110mcg) of the inhaled corticosteroid (ICS) fluticasone propionate metered-dose-inhaler (FP-MDI) for asthma. The objective was to assess health care practitioner (HCP) knowledge about FP-MDI dosing and side effects.

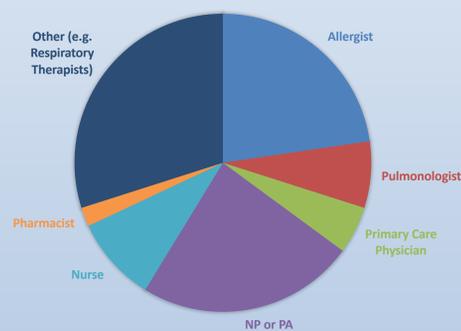
Materials & Methods

Methods

Anonymous and interactive polling was conducted using TurningPoint software and hand-held devices before and after PowerPoint presentation of the case during 40 live meetings of HCPs across the United States. During the presentation, education about FDA-approved FP-MDI doses and side effects was provided.

Participants

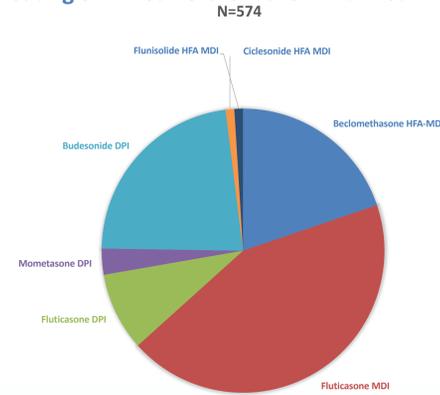
Background of Meeting Attendees (%)
N=728



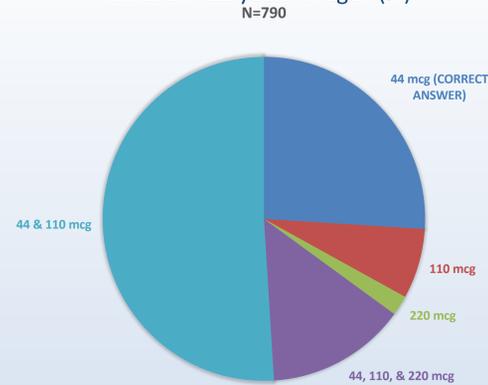
Results

Presentations (n=40) were delivered to 790 HCPs, including asthma specialists. Before the presentation, only 26% of HCPs knew the dose of FP-MDI that is FDA-approved for children <12 years of age (44mcg only), and only 28% were confident in their ability to detect and diagnose growth and adrenal suppression secondary to ICS in a child with asthma. After the presentation, the respective values were 97% and 89% (p<0.05). FP-MDI was the ICS with which 43% were most experienced, yet only 11% knew the Asthma Guideline-recommended medium dose of FP-MDI for 5-11 year old children (>176-352mcg daily). A high percentage (49%) indicated that between 21% and 80% of 5-11 year old children that they treat with FP-MDI receive the 110mcg dose.

With Which ICS Do You Have the Greatest Level of Experience in treating 5-11 Year-Old Children with Asthma? (%)



Which fluticasone MDI dosages are FDA-approved for asthma in children <12 years of age? (%)

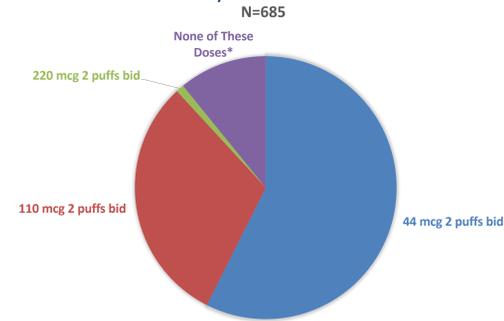


Do you feel confident in your ability to detect and diagnose growth and adrenal suppression secondary to ICS in a child with asthma? (%)



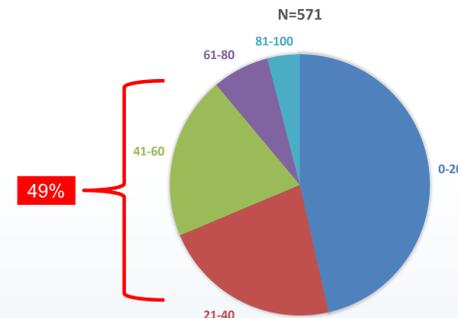
Results

What is the NHLBI Guideline-recommended "medium dose" of fluticasone MDI for 5-11 year old children with asthma? (%)

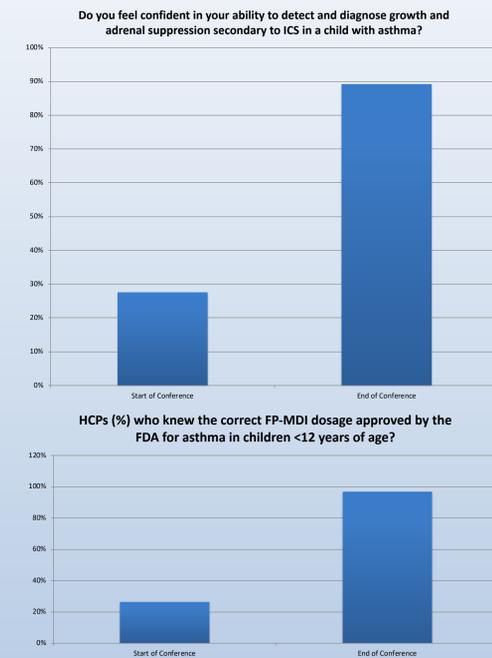


* Correct answer is >176-352mcg daily

Of all the 5-11 year old children with asthma that you treat with FP-MDI, what percentage receive the 110 mcg strength?



COMPARISON OF RESPONSES BEFORE AND AFTER PRESENTATION OF THE CASE (p<0.05)



Conclusion

HCPs are deficient in knowledge about FDA-approved FP-MDI doses and side effects and use FDA-unapproved doses, placing children at risk for developing serious systemic side effects. The reasons are unclear, but better methods to educate HCPs about ICS dosing and side effects are needed.

Limitations

- Findings are limited to HCP knowledge about one ICS in one age group. Future studies should focus on other drugs, including non-steroids, and other age groups, including adults.
- Did not investigate the reasons for the deficiencies in knowledge about FDA-approved FP-MDI doses and side effects.

Discussion

- The FDA approved all three FP-MDI doses (44, 110, 220 mcg) for adults, but did not approve the 110 mcg and 220 mcg doses for children because the dose-related risk of HPA axis suppression outweighed benefit.
- Most HCPs are unaware of the age-dependence of the FP-MDI FDA indication and use the higher unapproved doses "off-label".
- FP-MDI is the ICS most commonly associated with "off-label" prescribing and adrenal crisis in children in other countries.
- "Off label" prescribing is common, legal, often unknown by the prescribing physician, and unregulated by the FDA.
- Some of the most commonly prescribed "off-label" medications for children are used for allergy and asthma.
- Additional concerns are present when using inhaled corticosteroids and nasal or topical corticosteroids in the same children, which has not been well-studied.
- HCPs must be re-educated and better systems must be put into place to protect children, including at the levels of the FDA, pharmaceutical company, pharmacy, and electronic medical records.

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