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Use of Formoterol Fumarate for Bronchodilator Reversibility Testing in the Paediatric Population

Keywords: Formoterol Fumarate; Bronchodilator Reversibility; BDR; Asthma; Paediatrics; LABA; Symbicort

Abstract

Bronchodilator reversibility (BDR) testing is a vital tool in the objective diagnosis of paediatric asthma, as per current BTS, NICE, and SIGN guidelines. Salbutamol, a short-acting beta2 agonist (SABA), is typically used. However, we present a clinical case where Formoterol Fumarate, a fast-acting long-acting beta agonist (LABA), was successfully employed for BDR testing in a child with intolerance to Salbutamol. To our knowledge this is first case report of a 10 years old child where Budesonide/Formoterol was used for BDR. A 9% improvement in FEV1 was observed following the use of Symbicort Turbohaler® (Budesonide/Formoterol), closely approaching the 10% threshold for positive reversibility. Although evidence in children is limited, our case supports the consideration of Formoterol in select scenarios, particularly when adverse reactions to SABA therapies limit diagnostic assessment and also for those children who are on exclusively Budesonide/Formoterol (MART or AIR therapy).

Open Access Case Report

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Introduction

Asthma is one of the most common chronic conditions affecting children worldwide, with significant implications for quality of life, school attendance, and healthcare utilisation. Accurate diagnosis is essential, not only to initiate appropriate therapy but also to avoid unnecessary treatment in cases misdiagnosed as asthma. According to the latest 2024 joint guidelines issued by BTS, NICE, and SIGN, the diagnostic approach should incorporate a combination of clinical judgment and objective tests, including spirometry and bronchodilator reversibility (BDR) testing. BDR testing assesses the degree to which airway obstruction is reversible following administration of a bronchodilator [1,2].

Salbutamol, a short-acting beta2 agonist (SABA), is traditionally used for BDR due to its rapid onset of action and well-established efficacy. However, in some cases, children may experience exaggerated adverse reactions such as tachycardia, tremors, or headaches, which limit its use. Additionally, there is no universally agreed-upon agent or dosing strategy, creating an opportunity to explore other alternatives. One such alternative is Formoterol Fumarate, a long-acting beta agonist (LABA) with a rapid onset of action that makes it suitable for both maintenance and potential reversibility testing. In this report, we describe a case of a paediatric patient in whom Formoterol was used as part of BDR testing due to Salbutamol intolerance.

Materials and Methods

A 10-year-old boy with a history of moderate persistent asthma and associated atopy was seen at our paediatric respiratory clinic at Hull University Teaching Hospitals for diagnostic clarification and treatment optimisation. His baseline treatment included the Symbicort Turbohaler® 100/6 (a combination of Budesonide and Formoterol), administered at two puffs twice daily. This was chosen not only for its anti-inflammatory and bronchodilatory properties but also because the patient had previously experienced side effects from Salbutamol, including significant headaches and jitteriness.

As part of his assessment, baseline spirometry was performed, which revealed an FEV1 of 60% of the predicted value, with lower z scores (more than two standard deviations) of FEV1/FVC and a normal Z score for FVC, confirming airway obstruction. In accordance with national guidelines, bronchodilator reversibility testing was indicated. However, due to the patient's intolerance to Salbutamol, it was decided to use Formoterol via his own Symbicort Turbohaler®, which the patient was already prescribed as part of his regular regimen.

Two actuations of Symbicort 100/6 were administered under supervision, delivering a total dose of Budesonide 200 mcg and Formoterol 12 mcg. A repeat spirometry was conducted 15 minutes later, measuring post-bronchodilator lung function.

Results

The post-bronchodilator spirometry revealed a 9% improvement in FEV1 from the baseline value. Although this did not meet the guideline-defined threshold of 10% to be classified as a positive BDR [1], the improvement was nonetheless clinically meaningful. The patient tolerated the Formoterol well, with no immediate side effects reported during or after administration. The findings were interpreted in the clinical context, along with the patient's history of atopic conditions, previous wheezing episodes, and family history of asthma, to support the diagnosis.

Importantly, this case highlights not only the potential effectiveness of Formoterol as a substitute in specific patients but also the feasibility of using a patient's existing MART or AIR therapy inhaler in the clinical setting to assess airway reversibility.

Discussion

While the standard approach to BDR testing involves Salbutamol,

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our case underscores the need for flexibility in clinical practice, particularly in children with known intolerance. Formoterol Fumarate, unlike other LABAs such as Salmeterol, has a rapid onset of action (within 1–3 minutes), making it suitable for reversibility testing despite being classified as long-acting. Studies in adult populations, particularly among those with COPD, have established the efficacy of Formoterol in improving FEV1 within minutes of administration [3,4].

There is limited but growing evidence regarding the use of Formoterol in paediatric reversibility testing. Rechkina et al. (2018) conducted a prospective study on 36 paediatric patients aged 6 to 17 years with bronchial asthma and compared reversibility outcomes using Salbutamol and Formoterol [5]. The results demonstrated that Formoterol elicited comparable or even superior bronchodilation in some patients. Importantly, the authors recommended Formoterol as an option in patients with ambiguous or negative BDR results using Salbutamol or in those with poor tolerance to SABAs.

Our case supports these findings and illustrates that, under appropriate clinical circumstances, Formoterol may serve as a practical alternative. Additionally, using the child's own MART/AIR-therapy inhaler in the clinic for reversibility testing may enhance the relevance of results to real-world therapy and reduce unnecessary medication changes.

Conclusion

This case contributes to a limited but important body of evidence supporting the use of Formoterol Fumarate for BDR testing in children. For patients who cannot tolerate Salbutamol, Formoterol offers a rapid-onset, well-tolerated alternative that aligns with MART/AIR-therapy regimens increasingly used in paediatric asthma management. Broader research, ideally in the form of controlled studies or registries, is needed to standardise the use of Formoterol in this context and explore its role in refining diagnostic accuracy.

Conflicts of Interest

HSK has received speaker honorarium from Vertex Pharmaceuticals (Europe) Limited for an educational non-promotional talk. Other authors declare no conflict of interest.

Author Contributions

Conceptualization, H.S.K; Investigation, H.S.K., C.Q., and S.K.; Writing—Original Draft Preparation, C.Q.; Writing—Review and Editing, H.S.K., E.L. and S.K.

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