Uncontrolled asthmatics with small airways dysfunction (SAD) and response to extra-fine ICS/LABA formulation: A real-world, observational, effectiveness, multi-centre study from India (ERS 2025)

Asthma - management, Severe asthma, Treatments

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Background: Despite treatment, many asthmatics have uncontrolled asthma, and SAD is a key reason for poor control. We aimed to study the prevalence of SAD and efficacy of extra-fine formulation in uncontrolled asthmatics.

Methods: We recruited asthmatics across India who remained uncontrolled (ACQ >1.5) despite pharmacotherapy with ICS/LABA combination, in this real-world study. Participants were prescribed extra fine beclomethasone/formoterol combination via a pressurized metered dose inhaler 100/6 mcg 2 puffs bid for a period of 6 months. SAD was defined as FEF25-75 <65% predicted. Symptoms, asthma control (ACT), quality of life (AQLQ) and spirometry were assessed at baseline and 6 months.

Results: Of the 156 subjects recruited, we report the interim analysis of 57 subjects in table 1. [Mean age (± SD) 49.8 ± 13.8, Gender (M: F) % 45.6%:54.4%]. All subjects showed presence of SAD.

Variables	Baseline values (n= 57)	6 months after extra fine formulation treatment (n=57)	p-Values
Persistent Cough (%)	98.2%	49.1 %	p<0.001
Shortness of breath (%)	100%	52.6 %	p<0.001
Wheeze (%)	98.2%	40.3 %	p<0.001
Chest Tightness (%)	92.9%	7.02 %	p<0.001
FVC (L) (Mean ± SD)	1.97 ± 0.8	2.27 ± 0.9	p<0.001
FEV1(L) (Mean ± SD)	1.30 ± 0.6	1.58 ± 0.6	p<0.001
FEF25-75 Pre % Pred (Mean ± SD)	33.5 ± 15.7	45.3 ± 20.2	p<0.001
Mini ACQ -5 (Mean ± SD)	2.47 ± 1.7	0.80 ± 0.5	p<0.001
Mini AQLQ (Mean ± SD)	5.62 ± 0.7	6.45 ± 0.6	p<0.001

Conclusion: All uncontrolled asthmatics reported presence of SAD. Treatment with extra-fine Beclomethasone/Formoterol showed significant improvements in clinical and spirometry variables. This underscores the importance of SAD in patients with uncontrolled asthma and the potential role of extra-fine formulations in its management.