Extrafine Formulation Single-Inhaler Triple Therapy Improves Lung Function after Six Months of Treatment in Patients with Asthma: TriMaximize Study

TRIMAXIMIZE

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BACKGROUND:

- Randomized clinical trials have shown drug efficacy of extrafine formulation single-inhaler triple therapy (efSITT) consisting of beclomethasone dipropionate/formoterol fumarate/glycopyrronium (BDP/FF/G)[1].
- TriMaximize study was designed to observe patients who have switched to efSITT in a real-world setting over a period of one to three years.

METHODS:

- TriMaximize is a multinational, observational study that follows patients with asthma being prescribed efSITT. Patients were recruited in 125 centers across six countries (Germany, United Kingdom, Austria, Denmark, France and Spain).
- Pre-bronchodilator lung function was measured by spirometry and body plethysmography at baseline and after six months of treatment with efSITT along with additional descriptive analyses.

CONCLUSION:

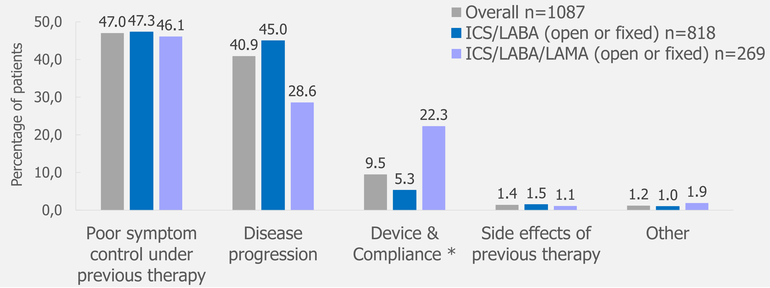
Significant improvement in lung function, including parameters of central (FEV_1) and peripheral (sRtot) airflow limitation as well as hyperinflation (RV/TLC) and reduction of rescue medication was observed six months after switching to efSITT from ICS/LABA or other combination of ICS/LABA/LAMA.

RESULTS:

Table 1. Baseline characteristics of patients (n=1090).

Age, mean years (±SD)		58 (15)
Sex, n (%)	Female	690 (63.3)
	Male	400 (36.7)
BMI (kg/m²), mean (±SD)		29.3 (7.8)
Smoking status, n (%)	Former smoker	340 (31.2)
	Current smoker	202 (18.5)
Pack years, mean (±SD)	Former smoker	19.1 (15.5)
	Current smoker	24.9 (15.5)
Time since stopped smoking, years (±SD)		14.8 (12.5)
Time since diagnosis at baseline visit, years (±SD)		14.4 (14.1)
FEV_1 % predicted at baseline visit, mean (±SD)		67.08 (16.96)
Rate of moderate or severe asthma exacerbations in previous year, mean (±SD)		1.8 (1.7)
Asthma maintenance treatment before switch to efSITT, n (%)	ICS/LABA (open or fixed)	821 (75.3)
	ICS/LABA/LAMA (open or fixed)	269 (24.7)
Classification according to GINA criteria, n (%)	GINA 4	878 (82.6)
	GINA 5	185 (17.4)

Figure 1. Main reasons for being prescribed BDP/FF/G.



*Device simplification or poor compliance under previous therapy due to multiple inhalers.

Table 2. Mean FEV_1 (±SD) at baseline (Visit 1), stratified by prior asthma maintenance treatment.

Overall n=856	2.03 L (0.82)
ICS/LABA (open or fixed) n=651	2.05 L (0.81)
ICS/LABA/LAMA (open or fixed) n=205	1.95 L (0.84)

Table 3. Mean change in lung function parameters after six months of treatment with BDP/FF/G, stratified by prior asthma maintenance treatment.

Parameters	Overall population	Prior ICS/LABA*	Prior ICS/LABA/LAMA*
FEV_1 (mL) (±SD)	**130** (460) p<0.0001 n=389	**150** (440) p<0.0001 n=312	**70** (540) p<0.2797 n=77
FEV_1 (% of predicted) (±SD)	**3.95** (13.51) p<0.0001 n=338	**4.09** (13.18) p<0.0001 n=278	**3.43** (14.85) p<0.0575 n=70
RV/TLC (% of predicted) (±SD)	**-7.79** (39.33) p=0.0017 n=256	**-9.07** (37.52) p=0.0007 n=205	**-2.64** (45.95) p=0.6828 n=51
sRtot (% of predicted) (±SD)	**-19.31** (84.52) p<0.0163 n=114	**-28.08** (80.04) p<0.0011 n=92	**17.37** (94.49) p=0.3983 n=22
MEF 25-75 (L/s) (±SD)	**0.10** (0.98) p=0.2430 n=142	**0.12** (0.85) p=0.1387 n=112	**0.01** (1.38) p=0.9656 n=30

For the mean change (V3-V1) only patients with spirometry and/or body plethysmography performed at Visit 1 and Visit 3 were included (a total of 453 patients, 355 were previously treated with ICS/LABA and 98 patients with ICS/LABA/LAMA).

*(fixed or open); FEV_1 - forced expiratory volume in 1 second; RV/TLC - residual volume to total lung capacity ratio; sRtot - total specific resistance; MEF 25-75 - maximum expiratory flow at 25-75% of FVC; ICS - Inhaled corticosteroid; LABA - Long-acting beta2-agonist; LAMA - Long-acting muscarinic antagonist.

Table 4. Total mean number of puffs (±SD) of rescue medication in the previous week at Visit 1 and Visit 3, stratified by prior asthma maintenance treatment.

	Visit 1	Visit 3
Overall	11.3 (11.9) n=665	7.4 (7.5) n=279
ICS/LABA (fixed or open)	10.8 (11.2) n=501	7.2 (7.2) n=215
ICS/LABA/LAMA (fixed or open)	12.7 (13.5) n=164	8.2 (8.3) n=64

Figure 2. Mean change in total number of puffs of rescue medication in the previous week V3-V1, stratified by prior asthma maintenance treatment (n=229).

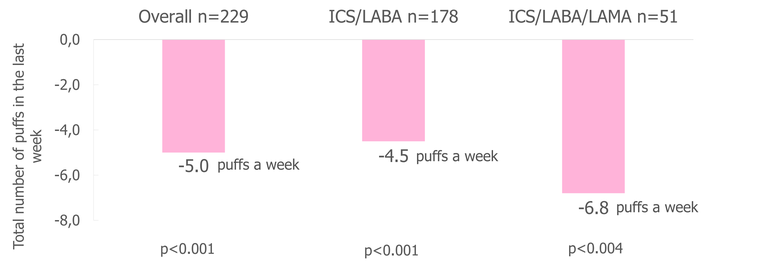
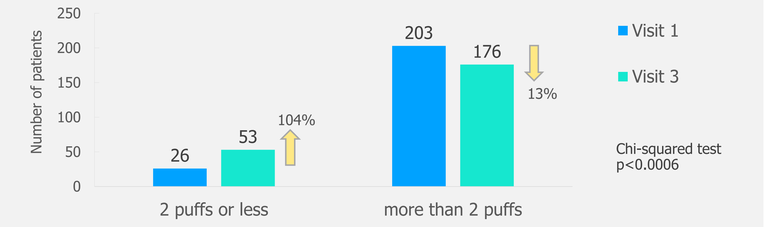


Figure 3. Number of patients taking a rescue medication in the previous week comparing Visit 1 and Visit 3 for high and low users (n=229).



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