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

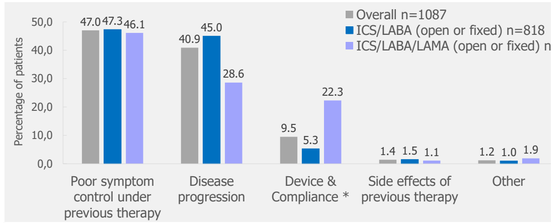
Significant improvement in lung function, including parameters of central (FEV_1) and peripheral (sRtot) airflow limitation as well as hyperinflation (RV/TLC) and reduction of rescue medication was observed six months after switching to efSITT from ICS/LABA or other combination of ICS/LABA/LAMA.

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 i

Table 2. Mean FEV1 (±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).

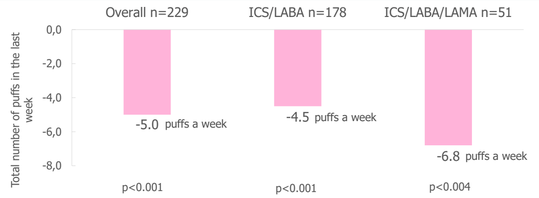
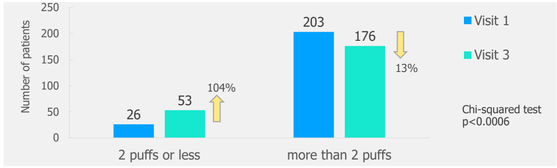


Figure 3. Number of patients taking a rescue medication in the previous week comparing Visit 1 and Visit 3 for high and low users (n=229).



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[1] Virchow J.C. et al., Single inhaler extrafine triple therapy in uncontrolled asthma (TRIMARAN and TRIGGER): two double-blind, parallel-group, randomised, controlled phase 3 trials. The Lancet, 2019. 394(10210): p. 1737-1749.
[2] Schatz M. et al., Asthma Control Test: reliability, validity, and responsiveness in patients not previously followed by asthma specialists. J Allergy Clin Immunol, 2006. 117: p. 549-556.

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