Real-World Evidence for Fixed Triple Therapy with Beclomethasone/Formoterol/Glycopyrronium in Asthma Patients with Concomitant COPD: Six-Month Results of TriMaximize

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BACKGROUND:

- Randomized clinical trials have shown clinical efficacy of extrafine formulation single-inhaler triple therapy consisting of beclomethasone dipropionate/formoterol fumarate/glycopyrronium (BDP/FF/G)[1].
- TriMaximize study observes patients who have switched to BDP/FF/G 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 who have been prescribed BDP/FF/G (87/5/9 µg). Patients were recruited at 125 sites across six countries (Germany, United Kingdom, Austria, Denmark, France and Spain).
- Asthma control is assessed by the Asthma Control Test (ACT) and Health-Related Quality of Life is evaluated by Mini Asthma Quality of Life Questionnaire (Mini AQLQ). Pre-bronchodilator lung function was assessed by spirometry and body plethysmography.

CONCLUSIONS:

- Significant improvement in asthma control, quality of life and lung function are seen six months after initiating treatment with BDP/FF/G.
- Effects were similar in patients with and without concomitant COPD.
- TriMaximize indicates comparable efficacy in this clinically relevant yet under-investigated subgroup in a real-world setting.

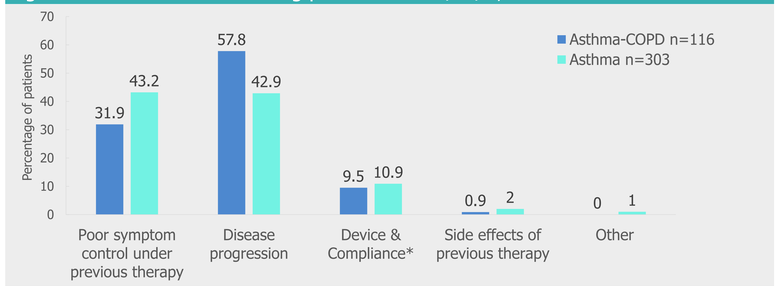
RESULTS:

Table 1. Baseline characteristics, n=419.

		Asthma-COPD n=116	Asthma n=303	Overall n=419
Age, mean years (±SD)		63 (11)	57 (16)	59 (15)
Sex, n (%)	Female	64 (55.2)	181 (59.7)	245 (58.5)
	Male	52 (44.8)	122 (40.3)	174 (41.5)
BMI (kg/m^2), mean (±SD)		28.3 (6.4)	29.2 (6.5)	29.0 (6.5)
Smoking status, n (%)	Former smoker	54 (46.6)	88 (29.0)	142 (33.9)
	Current smoker	29 (25.0)	47 (15.5)	76 (18.1)
	Never smoker	33 (28.4)	168 (55.4)	201 (48.0)
Pack years, mean (±SD)	Former smoker	26.6 (15.1)	18.5 (15.2)	20.4 (15.5)
	Current smoker	30.7 (14.1)	23.8 (13.9)	26.4 (14.3)
Time since stopped smoking, years (±SD)		10.2 (8.4)	15.6 (13.0)	13.5 (11.7)
Time since diagnosis at baseline visit, years (±SD)		12.6 (12.4)	14.1 (14.5)	13.7 (14.0)
Rate of moderate or severe asthma exacerbations in previous year, mean (±SD)		2.1 (1.2)	1.7 (1.5)	1.8 (1.4)
Asthma maintenance treatment before switch to BDP/FF/G, n(%)	ICS/LABA *	88 (75.9)	241 (79.5)	329 (78.5)
	ICS/LABA/LAMA*	28 (24.1)	62 (20.5)	90 (21.5)

*open or fixed

Figure 1. Main reasons for being prescribed BDP/FF/G, n=419.



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

Figure 2. Change of ACT category at baseline and after six months.

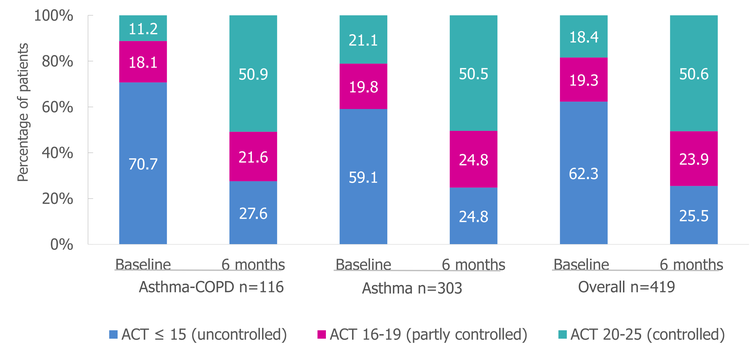
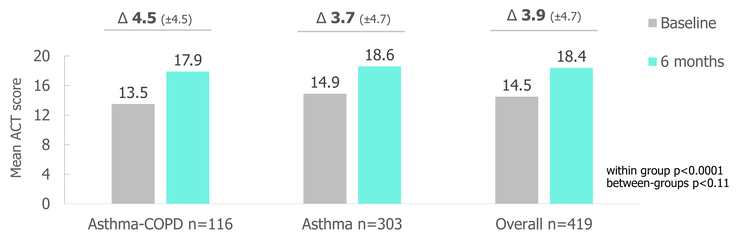
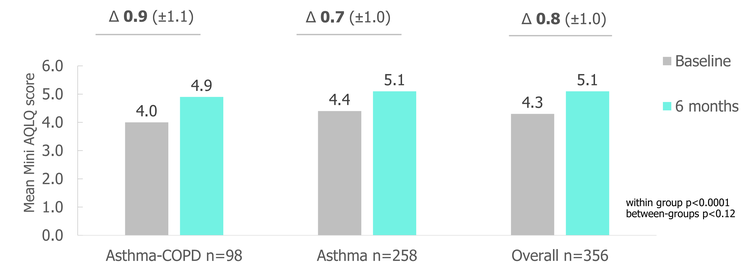


Figure 3. Change of mean ACT score (±SD) at baseline and after six months.



Minimal clinically important difference (MCID) for ACT of 3 points was met and exceeded.

Figure 4. Change of mean Mini-AQLQ score (±SD) at baseline and after six months.



MCID for Mini AQLQ of 0.5 points was met and exceeded.

Table 2. Mean change in lung function parameters after six months of treatment with BDP/FF/G.

Parameters	Asthma-COPD	Asthma	Overall	Pairwise t-tests (between-groups)
FEV_1 (mL) (±SD)	**110** (450) p=0.0225 n=92	**130** (480) p<0.0001 n=213	**120** (470) p<0.0001 n=305	p=0.7190
FEV_1 (% of predicted) (±SD)	**2.99** (15.51) p=0.0710 n=90	**4.05** (12.37) p<0.0001 n=191	**3.71** (13.44) p<0.0001 n=281	p=0.5707
RV/TLC (%) (±SD)	**-1.43** (13.84) p=0.3811 n=73	**-3.12** (9.80) p=0.0002 n=147	**-2.56** (11.30) p=0.0009 n=220	p=0.3531
sRtot (kPa*s) (±SD)	**-0.16** (1.19) p=0.4664 n=29	**-0.14** (0.54) P=0.0460 n=65	**-0.14** (0.79) p=0.0809 n=94	p=0.9036
MEF 25-75 (ml/s) (±SD)	**120** (750) p=0.2463 n=57	**100** (1090) p=0.4787 n=61	**110** (940) p=0.2144 n=118	p=0.9205

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.

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References:

[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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