Long-Term Asthma Control with Beclometasone/Formoterol/Glycopyrronium: 12-Month Results of TriMaximize Study

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TRIMAXIMIZE

BACKGROUND:

- Randomized clinical trials have shown clinical efficacy of extrafine formulation single-inhaler triple therapy consisting of beclometasone dipropionate/formoterol fumarate/glycopyrronium (BDP/FF/G)[1].
- TriMaximize study observes patients who have been 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 moderate to severe asthma who have been prescribed BDP/FF/G in medium (87/5/9 µg) or high strength (172/5/9 µg). Patients were recruited at 162 sites across eight countries (Germany, United Kingdom, Austria, Denmark, France, Spain, Poland and Italy).
- Asthma control is assessed by the Asthma Control Test (ACT). The Minimal clinically important difference (MCID) for ACT is 3 points.

Table 1. Baseline characteristics of the patients.

Parameters		Overall population n=1,445	Medium strength (87/5/9 µg) n=1,084	High strength (172/5/9 µg) n=361
Age (years), mean (±SD)		57.9 (15.0)	57.9 (14.8)	56.4 (15.4)
Sex, n (%)	Female	907 (62.8)	685 (63.2)	222 (61.5)
	Male	538 (37.2)	399 (36.8)	139 (38.5)
BMI (kg/m^2), mean (±SD)		28.9 (6.4)	28.8 (6.4)	29.2 (6.5)
Smoking status, n (%)	Never smoker	755 (52.2)	561 (51.8)	194 (53.7)
	Current smoker	259 (17.9)	203 (18.7)	56 (15.5)
	Former smoker	431 (29.8)	320 (29.5)	111 (30.7)
Time since stopped smoking (years)* (±SD)		14.7 (12.4)	14.1 (12.2)	16.5 (13.1)
Time since diagnosis at baseline visit, years (±SD)		15.1 (14.7)	13.6 (13.6)	19.7 (16.8)
Concomitant diseases, n (%)		1161 (85.3)	847 (84.1)	314 (88.7)
	Arterial hypertension	507 (37.8)	392 (39.2)	115 (33.7)
	COPD	298 (22.4)	255 (25.7)	43 (12.8)
Rate of moderate or severe asthma exacerbations in previous year, mean (±SD)		1.8 (1.6)	1.8 (1.5)	2.0 (1.9)
Classification according to GINA criteria, n (%)	GINA Step 4	1079 (76.3)	913 (85.3)	166 (48.3)
	GINA Step 5	335 (23.7)	157 (14.7)	178 (51.7)
Previous treatment	ICS/LABA**	1050 (72.7)	854 (78.8)	196 (54.3)
	ICA/LABA/LAMA**	395 (27.3)	230 (21.2)	165 (45.7)

* restricted to former smokers
**fixed or free

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RESULTS:

Figure 1. Change of ACT score categories at baseline and after 3 and 12 months in overall population (a), stratified by medium or high strength of BDP/FF/G (b) and by prior maintenance treatment (c).

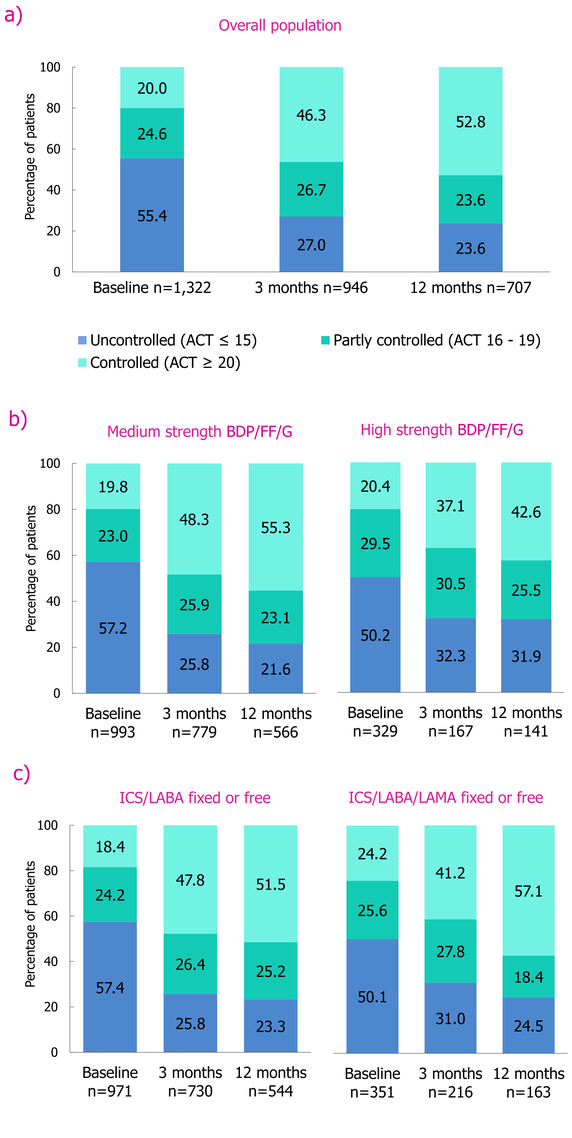
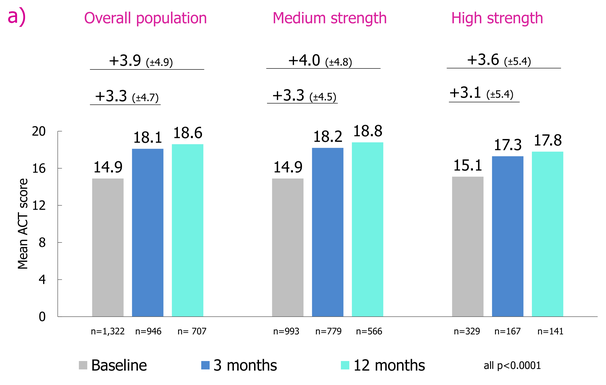
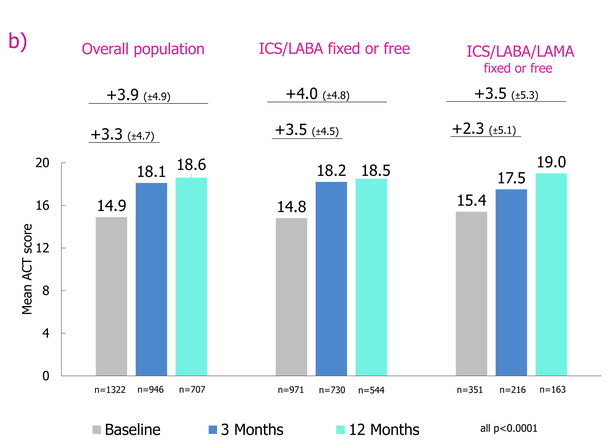


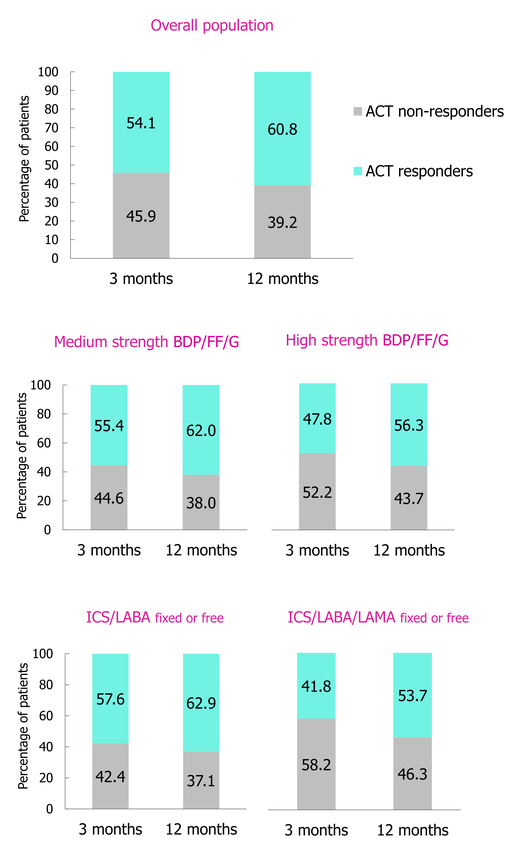
Figure 2. Mean change in ACT score (±SD) at 3 and 12 months of treatment, stratified by medium or high strength of BDP/FF/G (a), and by prior maintenance treatment (b).





After 12 months of treatment, the MCID of 3 points for ACT score was met or exceeded in the overall population (both dosage strengths), as well as in patients previously treated with ICS/LABA or ICS/LABA/LAMA (all p<0.0001).

Figure 3. ACT Responders - percentage of the patients who achieved the MCID of 3 points for the ACT score after 3 and 12 months (a), stratified by medium or high strength of BDP/FF/G (b) and by prior maintenance treatment (c).



Overall, 60.8% of patients exceeded the MCID of 3 points for ACT and were classified as responders.

CONCLUSIONS:

- Significant improvement in asthma control in patients with moderate to severe asthma after 12 months of treatment with extrafine formulation of BDP/FF/G suggests that this triple therapy is a beneficial long-term treatment option for asthma patients.

References:

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[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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