

Improvement in Lung Function after Six Months of Treatment with Extrafine Formulation Single-Inhaler Triple Therapy (efSITT) in Patients with Asthma - TriMaximize Study

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TRIMAXIMIZE

BACKGROUND:

The TriMaximize study observes patients who have switched to extrafine formulation single-inhaler triple therapy (efSITT) consisting of **beclomethasone dipropionate/formoterol fumarate/glycopyrronium (BDP/FF/G)** in a real-world setting. The clinical efficacy and safety of efSITT has already been shown in clinical trials¹.

METHODS:

- This is a multinational, observational study that follows patients with asthma being prescribed efSITT over a period of one to three years. Patients were recruited at 125 sites across six countries (DE, UK, AT, DK, FR and ES). Here we present the data from the interim analysis after 6 months of observation.
- 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.

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/m ²), 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)
	ICS/LABA*	67.73 (16.56)
	ICS/LABA/LAMA*	64.97 (18.10)
Exacerbation rate in the past year, mean (±SD)		1.8 (1.7)
Asthma maintenance treatment before switch to efSITT, n (%)	ICS/LABA*	821 (75.3)
	ICS/LABA/LAMA*	269 (24.7)
Classification according to GINA criteria, n (%)	GINA Step 4	878 (82.6)
	GINA Step 5	185 (17.4)

*(fixed or open)

RESULTS:

Table 2. Mean change from baseline 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 only patients with spirometry and/or body plethysmography performed at baseline and month six were included (a total of 453 patients, 355 were previously treated with ICS/LABA and 98 patients with ICS/LABA/LAMA).

*(fixed or open); FEV₁ - forced expiratory volume in 1st second; RV/TLC - residual volume to total lung capacity ratio; sRtot - total specific resistance; MEF 25-75 - maximum expiratory flow at 25-75% of forced vital capacity (FVC); ICS - Inhaled corticosteroid; LABA - Long-acting beta2-agonist; LAMA - Long-acting muscarinic antagonist.

Figure 1. Mean change in total number of puffs of rescue medication in the week before baseline and at month six, stratified by prior asthma maintenance treatment (n=229).

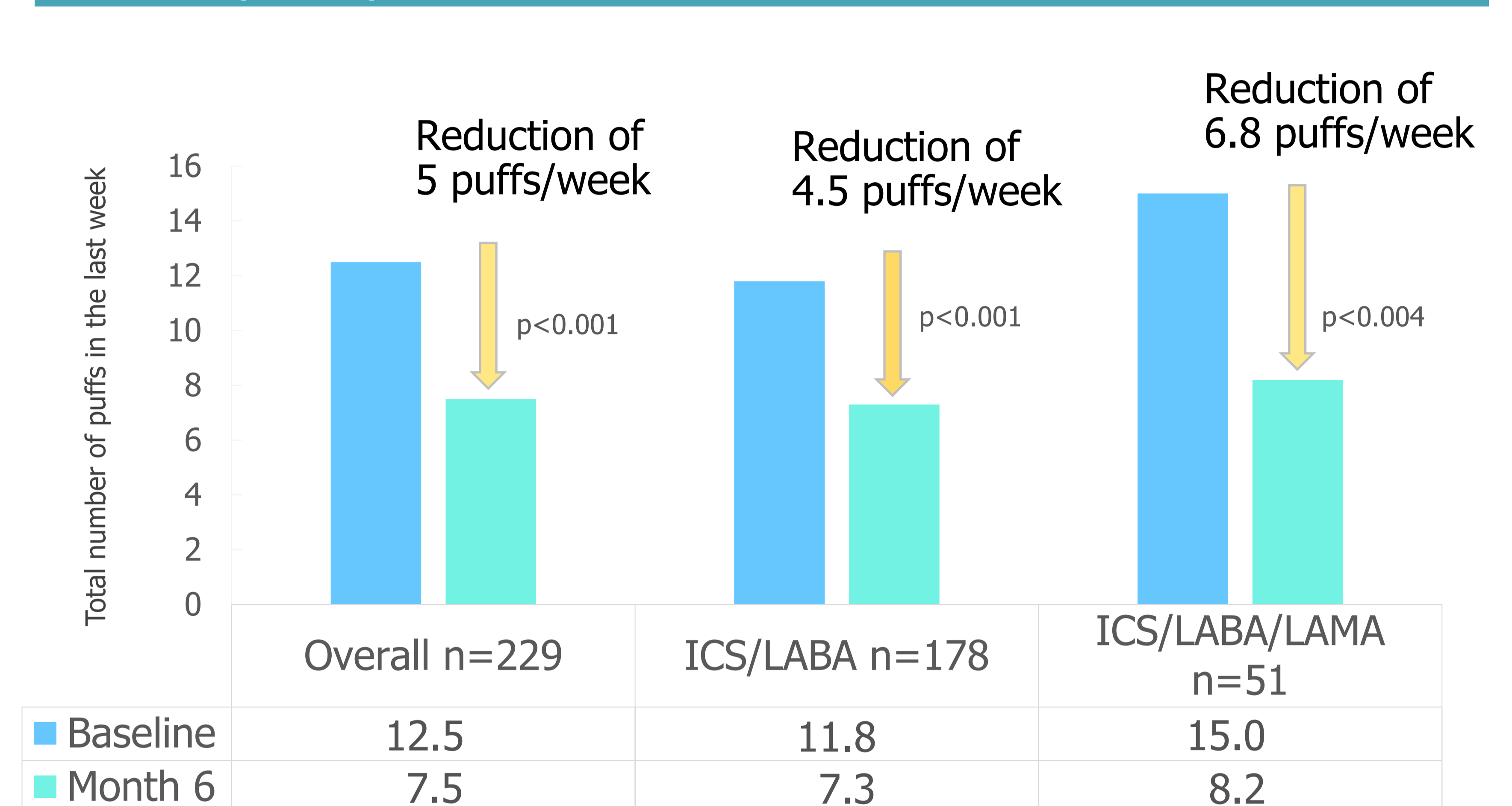
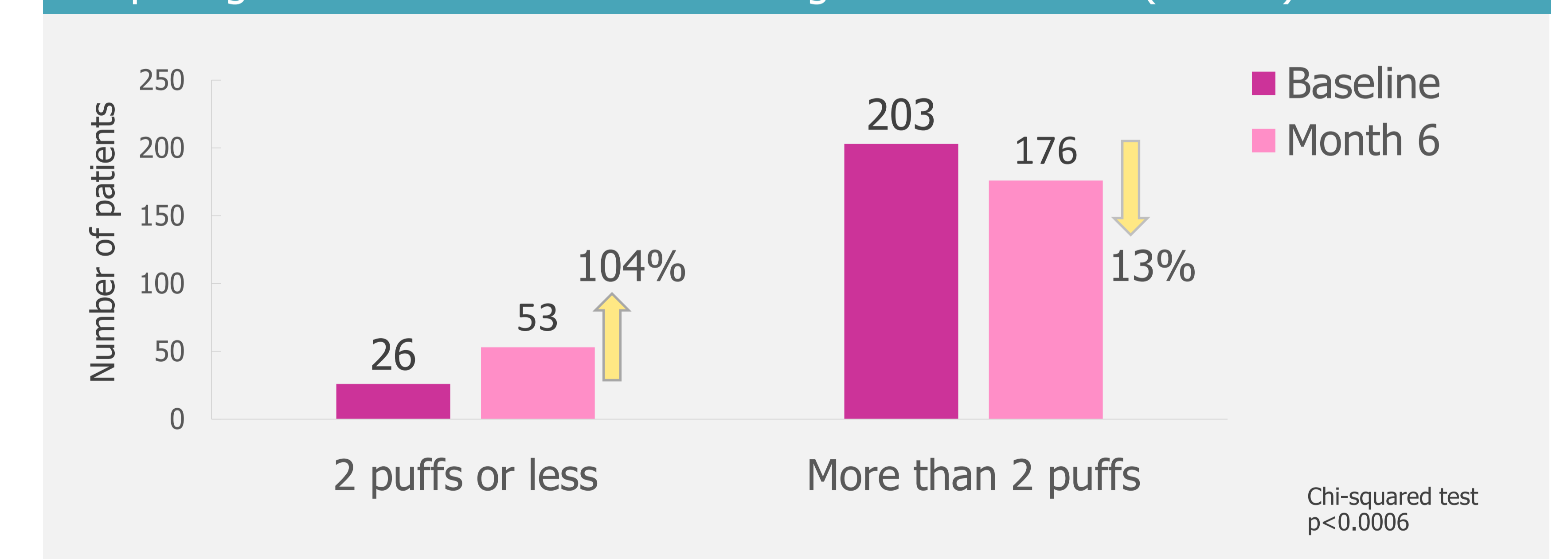


Figure 2. Number of patients taking a rescue medication in the previous week comparing baseline and month six for high and low users (n=229).



CONCLUSION:

Significant lung function improvement and reduction in rescue medication use were observed in asthma patients six months after switching to efSITT. This especially includes parameters of peripheral obstruction (sRtot) and hyperinflation (RV/TLC).



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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.

The TriMaximize study was funded by Chiesi. CG, RR, CSU, WP, VP, AB and FT have received fees for conducting the study. VB and DN are employees of Chiesi GmbH.