

# Exacerbation Reduction and Improved Quality of Life in Asthma with Extrafine Formulation Single-Inhaler Triple Therapy (efSITT): Six-Month Results of the TriMaximize Study

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TRIMAXIMIZE

## BACKGROUND:

- The TriMaximize study was designed to observe patients who have switched to extrafine formulation single-inhaler triple therapy consisting of **beclomethasone dipropionate/formoterol fumarate/glycopyrronium (BDP/FF/G)** in a real-world setting over a period of one to three years.

## METHODS:

- This is a multinational, observational study that follows patients with asthma being prescribed efSITT. 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.
- Descriptive analyses of Health-Related Quality of Life (HRQoL) evaluated by Mini Asthma Quality of Life Questionnaire (Mini AQLQ)<sup>1</sup> and exacerbation rates were performed.

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 <sup>2</sup> ), 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 <sub>1</sub> % predicted at baseline visit, mean (±SD)		67.08 (16.96)
Exacerbation rate in the past year, mean (±SD)		1.8 (1.7)
Asthma maintenance treatment before switch to efSITT, n (%)	ICS/LABA (fixed)	787 (72.2)
	ICS/LABA (open)	34 (3.1)
	ICS/LABA/LAMA (fixed)	17 (1.6)
	ICS/LABA/LAMA (open)	252 (23.1)
Classification according to GINA criteria, n (%)	GINA Step 4	878 (82.6)
	GINA Step 5	185 (17.4)

## RESULTS:

Figure 1. Proportion of patients at baseline with one and two or more exacerbations (±SD) in the last 12 months under previous treatment, n=1090.

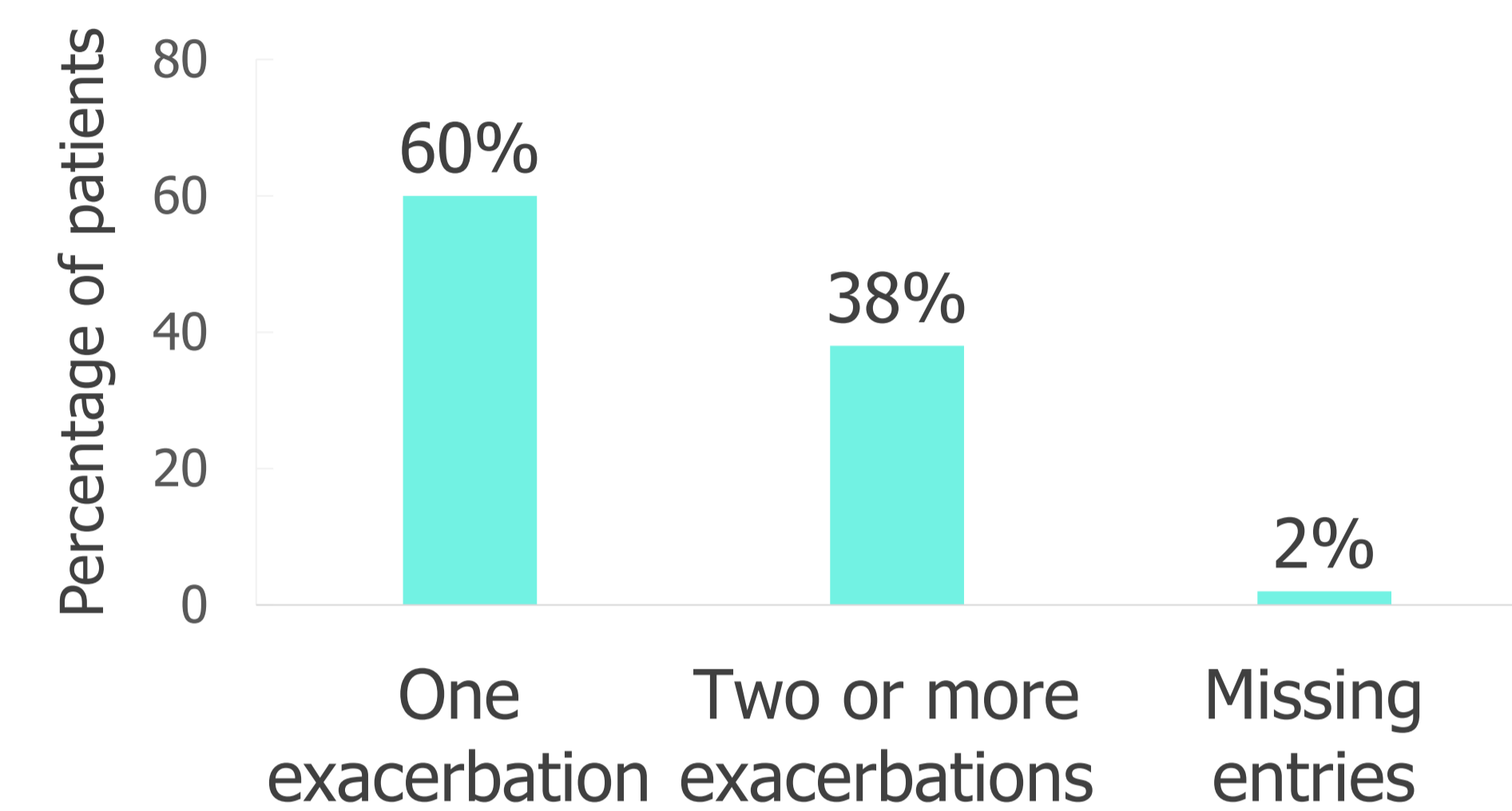


Figure 2. Severity of exacerbations at baseline in the last 12 months under previous treatment, n=1090.

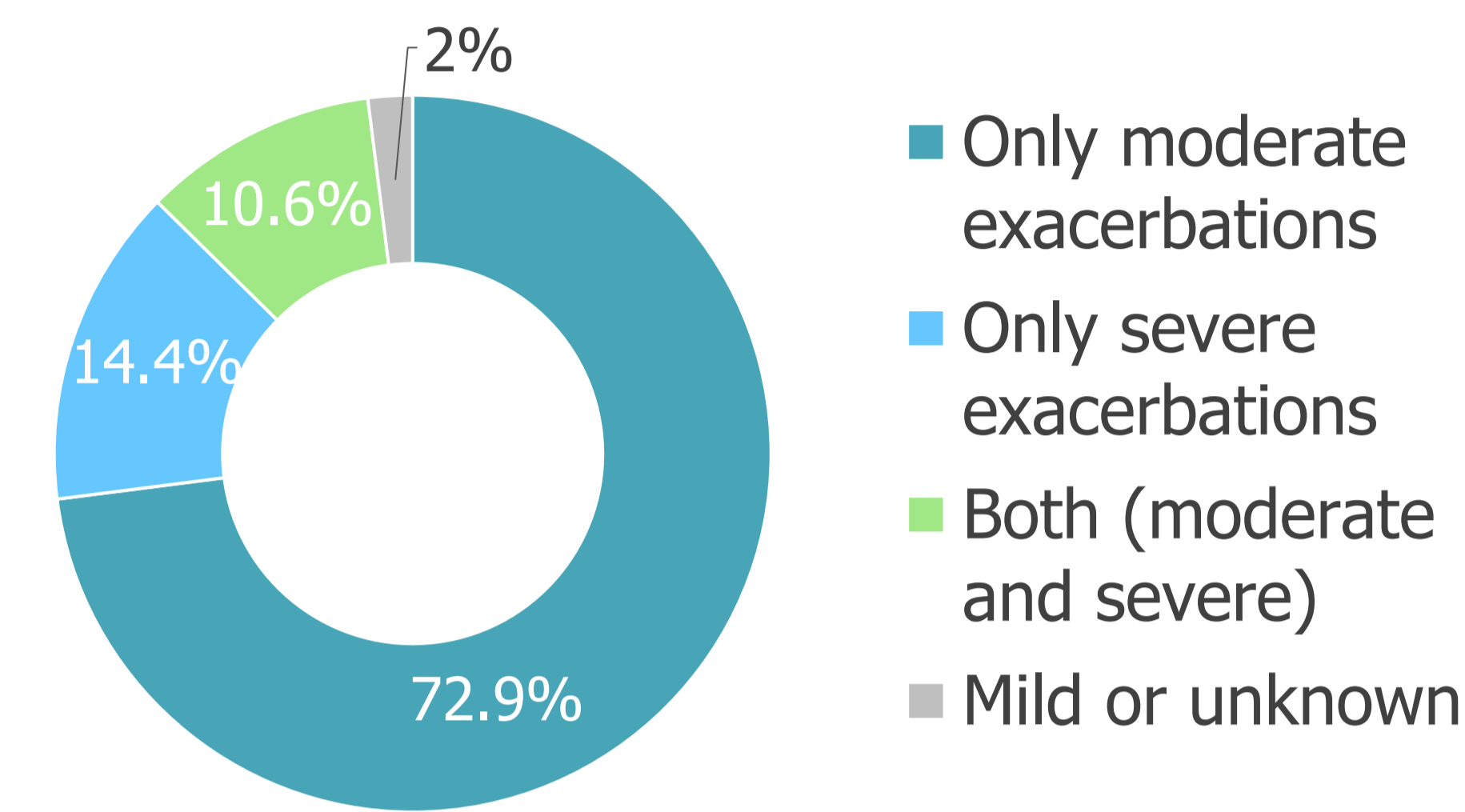


Figure 3. Mean exacerbation rate at baseline and after six months, stratified by prior asthma maintenance treatment.

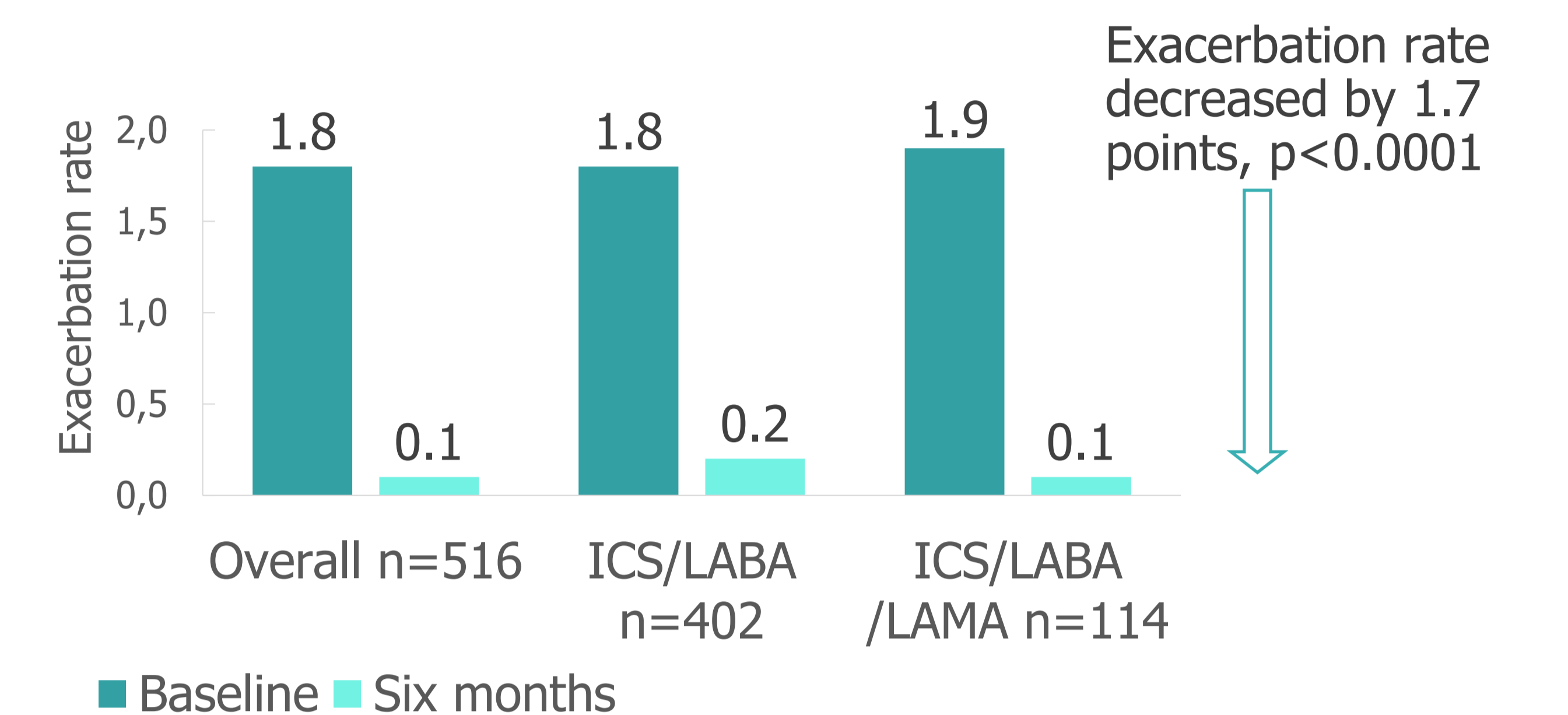


Figure 4. Asthma-related impairment of Health-Related Quality of Life (HRQoL) according to Mini AQLQ score at baseline and after six months (n=385).

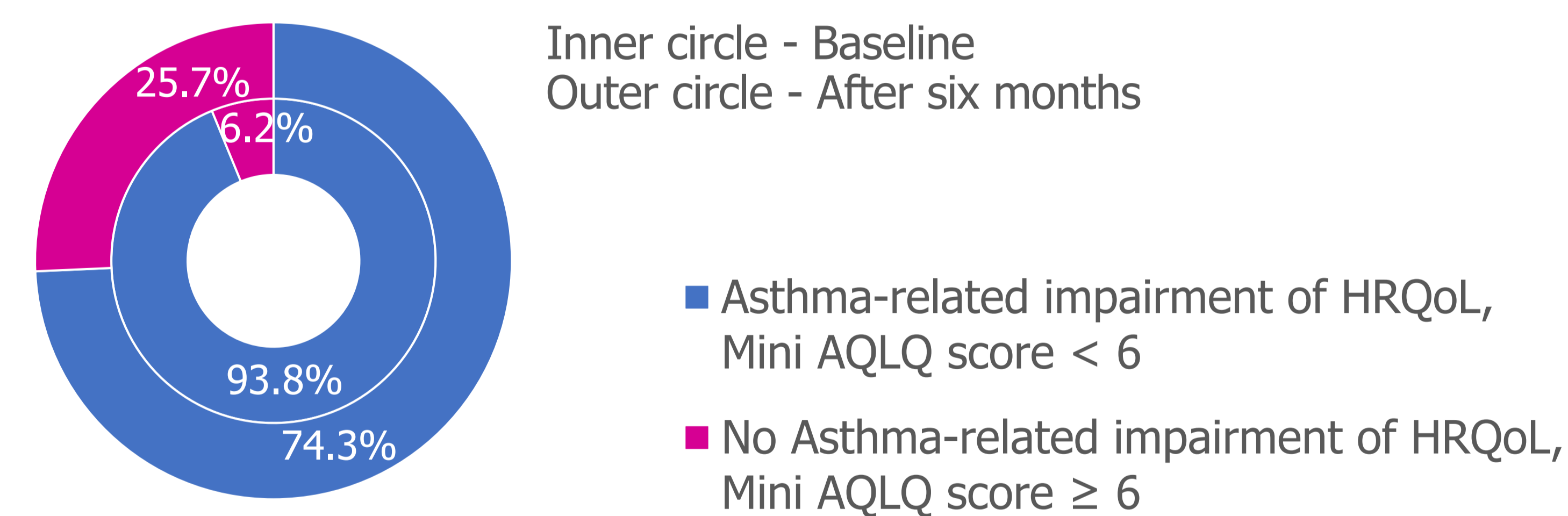


Figure 5. Mean Mini AQLQ score including the sub-domains at baseline and after six months (n=385).

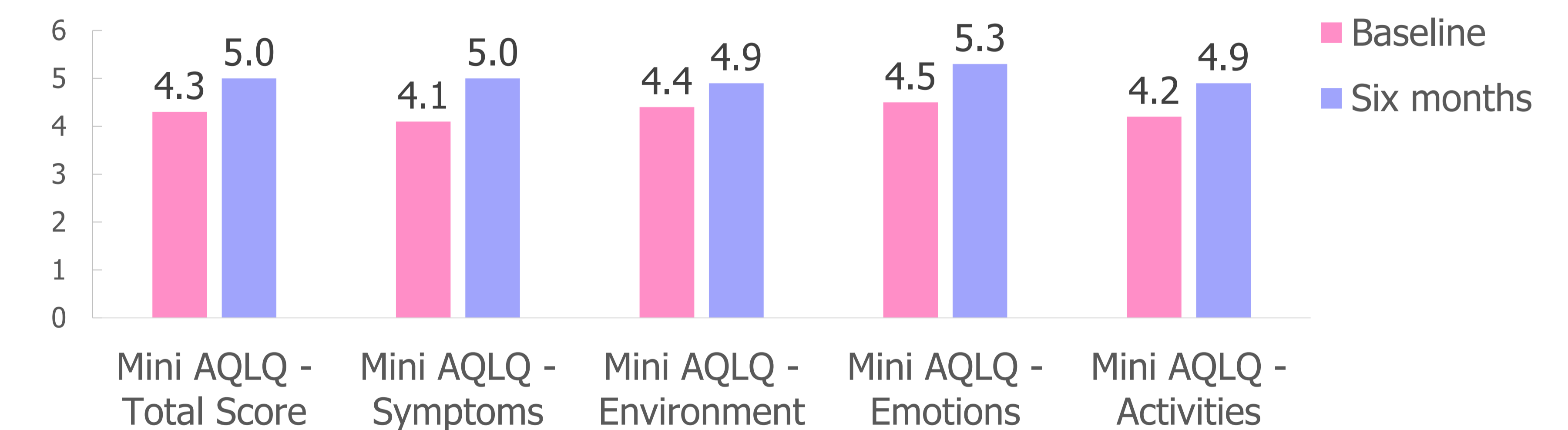


Figure 6. Change in mean Mini AQLQ domains scores after six months, stratified by prior asthma maintenance treatment (overall n=385, ICS/LABA n=318, ICS/LABA/LAMA n=67, all p<0.0001, except ICS/LABA/LAMA environment p<0.0293).

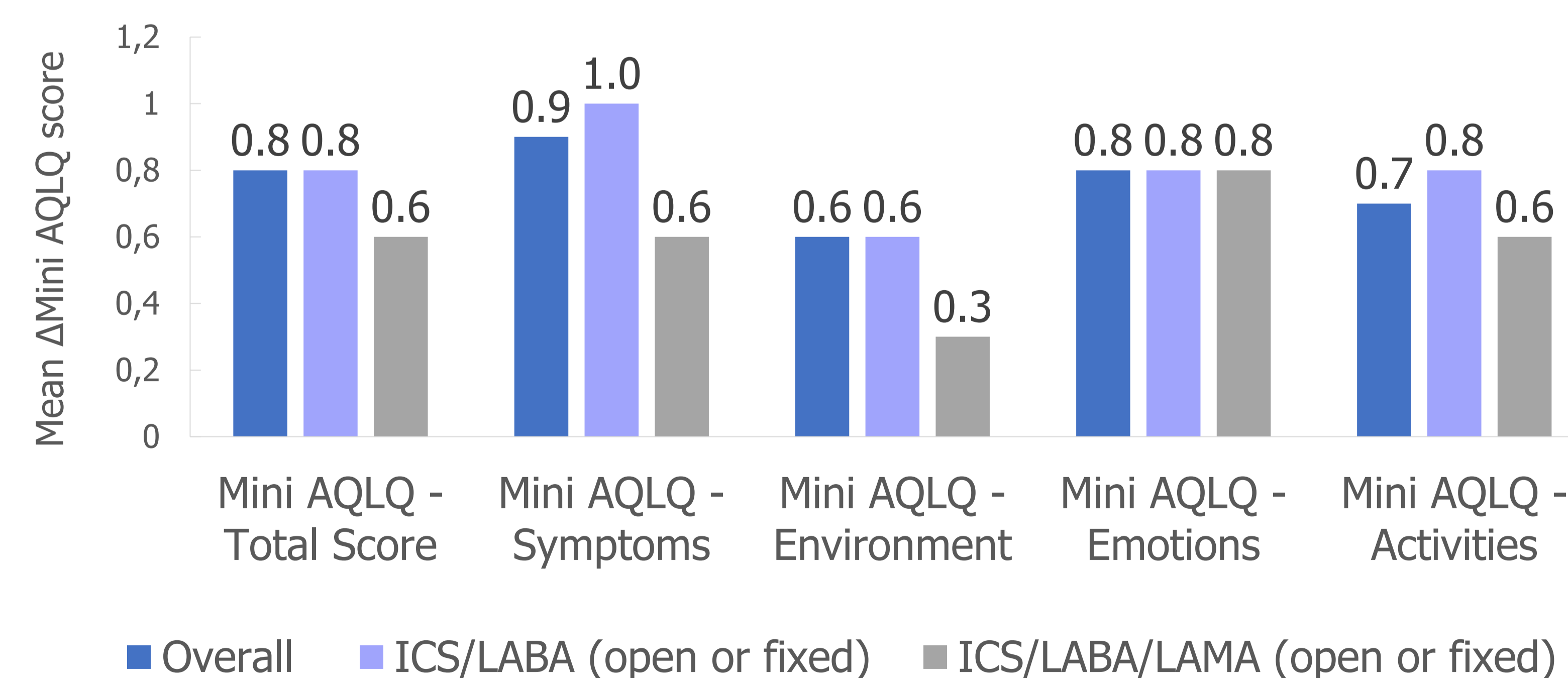


Table 2. Responders for Mini AQLQ score at six months of treatment according to MCID ≥ 0.5 points, stratified by prior asthma maintenance treatment.

Prior asthma maintenance treatment	Patients with mean ΔMini AQLQ score ≥ 0.5, n (%)
ICS/LABA (open or fixed) n=318	182 (57.2)
ICS/LABA/LAMA (open or fixed) n=67	34 (50.7)
Overall n=385	<b>216 (56.1)</b>

Overall, 56.1% of patients met or exceeded the MCID of 0.5 points for the Mini AQLQ and were classified as responders.

## CONCLUSIONS:

Exacerbation reduction and improvement in HRQoL were observed six months after switching to efSITT from dual as well as free triple combinations.

Minimal clinically important difference (MCID) for Mini AQLQ score of 0.5 points was met or exceeded in the overall population and in the patients on prior ICS/LABA and ICS/LABA/LAMA.

### Reference:

<sup>1</sup>Development and validation of the Mini Asthma Quality of Life Questionnaire, EF Juniper, GH Guyatt, FM Cox, PJ Ferrie, DR King European Respiratory Journal 1999 14: 32-38; DOI: 10.1034/j.1399-3003.1999.14a08.x

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