

20. – 23. März 2024

64. Kongress der DGP

Pneumologie - sektorenübergreifend, modern und lebendig
Rosengarten Mannheim

64. DGP Kongress – 20. – 23. März 2024

Weitere Einblicke aus dem Bereich *Asthma*

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Remission als langfristiges Ziel der medikamentösen Asthma-Therapie¹

„Das generelle Therapiekonzept besteht nicht mehr in der Reaktion auf Symptome, sondern in der nachhaltigen Prävention ihres Auftretens, mit dem Ziel, eine bestmögliche Asthma-Kontrolle (Tab. 5) oder eventuell sogar eine Asthma-Remission mit so wenigen Medikamenten als möglich und mit so wenigen Nebenwirkungen als möglich zu erreichen.“¹

Asthma-Kontrolle vs. Asthma-Remission¹

- **Asthma-Kontrolle** = Symptomkontrolle über **kurzen Zeitraum (Wochen)**; systemische Glucocorticoide sind nicht ausgeschlossen
- **Asthma-Remission** = vollständige Abwesenheit jeglicher Asthma-Symptomatik über **längeren Zeitraum (mind. 1 Jahr)**; systemische Glucocorticoide sind ausgeschlossen

Kriterien für eine Asthma-Remission – alle Kriterien müssen erfüllt sein
Dauerhafte (≥ 12 Monate) Abwesenheiten von Asthma-Symptomen
Dauerhafte (≥ 12 Monate) Abwesenheit von Exazerbationen
Stabile Lungenfunktion
Kein Bedarf an systemischen Glucocorticoiden für die Behandlung von Asthma

Formen der Asthma-Remission¹:

- spontan (z. B. transiente Asthmaformen in der Kindheit)
- off treatment (z.B. nach einer therapeutischen Maßnahme)
- on treatment (unter einer laufenden Dauer-Therapie)

1) S2K-Leitlinie zur fachärztlichen Diagnostik und Therapie von Asthma 2023; <https://register.awmf.org/de/leitlinien/detail/020-009>.

Association between the Asthma Control and Health-Related Quality of Life after Six Months of Treatment with Extrafine Single-Inhaler Triple Therapy in TriMaximize Study

T. Greulich¹; V. Bogoevska²; D. Nachtigall²; B. Akyildiz², B. Licht², R. Slawinska², C. Gessner^{3*}.

¹PneumoPraxis Marburg, Marburg; ²Chiesi GmbH, Hamburg; ³Specialized Practice for Pulmonary Medicine Leipzig,
*Corresponding author: ch.gessner@pneumologe-leipzig.de

TR:MAXIMIZE

Background:

- Randomized clinical trials have shown drug efficacy of extrafine 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 real-world setting over a period of one to three years.



Primary objective

To describe patient characteristics and therapy pathways for patients with a diagnosis of moderate-to-severe asthma who are treated with extrafine BDP/FF/G in real-world practice.

Secondary objectives

- To assess asthma control, quality of life, treatment adherence, healthcare resource utilization, treatment satisfaction with and tolerability of extrafine BDP/FF/G.
- To analyse parameters of lung function, incidence and severity of asthma exacerbations, use of rescue medication and systemic corticosteroids.

¹ Virchow 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.

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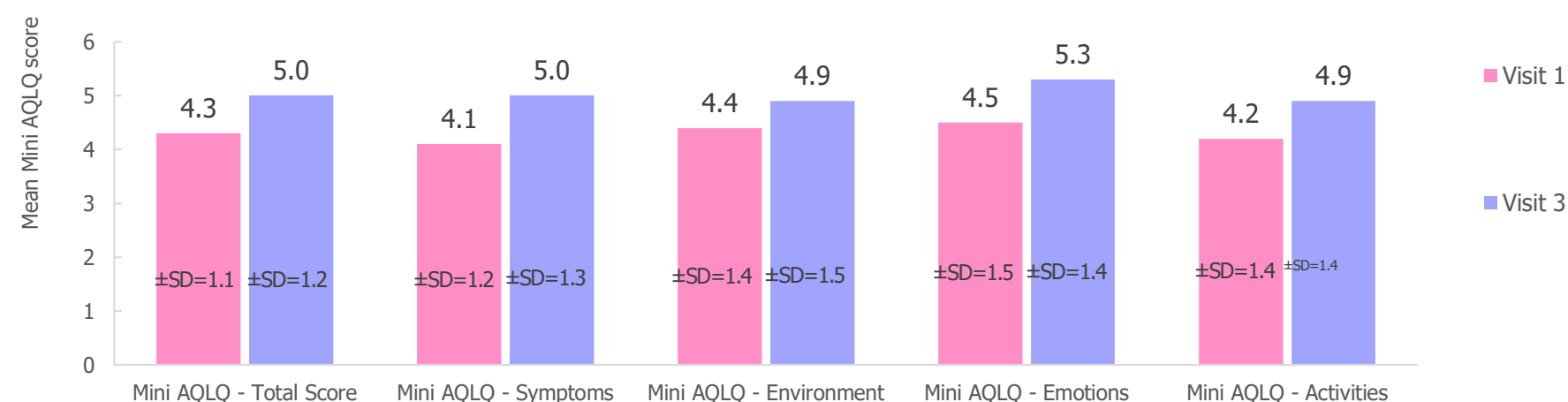
Results



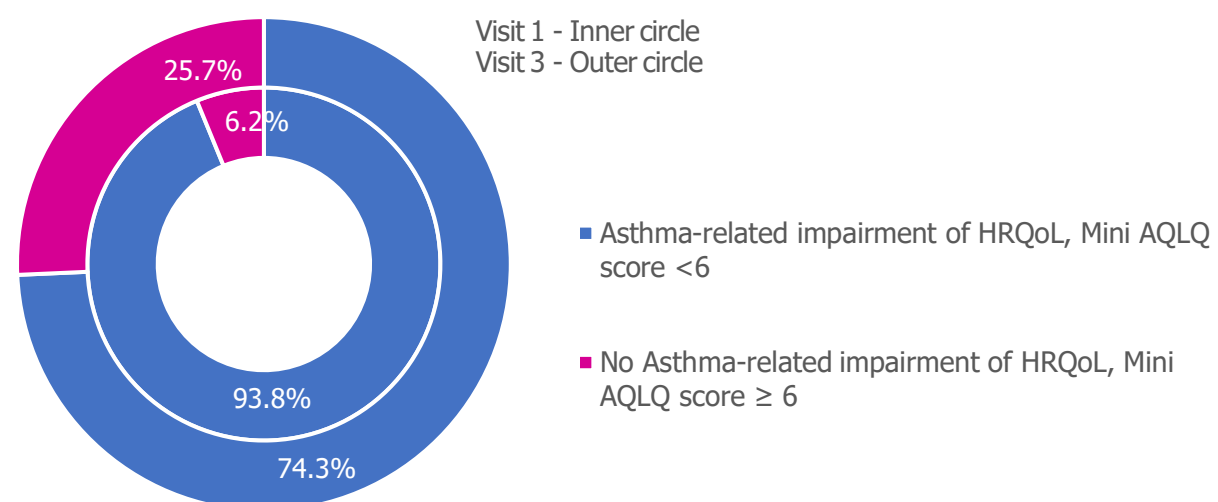
Baseline characteristics of patients (n=1090).

Age (years), mean (\pm SD)		58 (15)
Sex, n (%)	Female	690 (63.3)
	Male	400 (36.7)
BMI (kg/m ²), mean (\pm SD)		29.3 (7.8)
Smoking status, n (%)	Former smoker	340 (31.2)
	Current smoker	202 (18.5)
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)

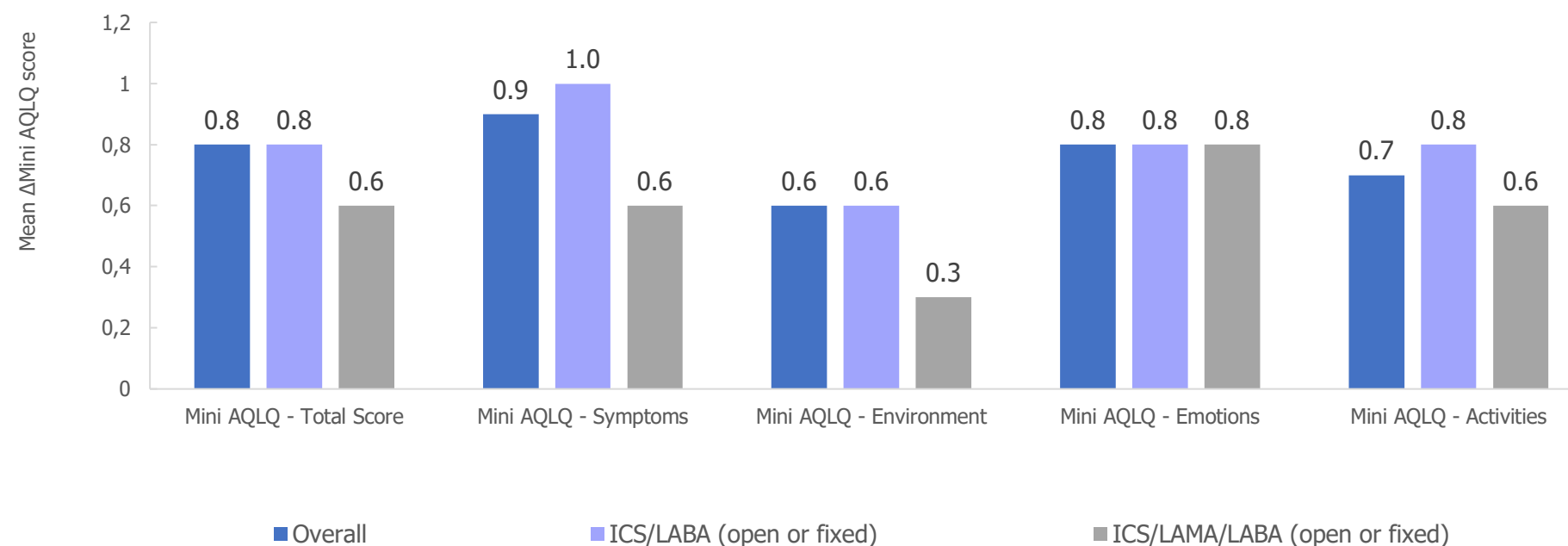
Mean Mini AQLQ score including the domains at Visit 1 and Visit 3 (n=385).



Asthma-related impairment of Health-Related Quality of Life (HRQoL) according to Mini AQLQ* score at V1 and V3 (n=385).



Change in Mini AQLQ domains scores (V3-V1) stratified by prior asthma maintenance treatment (overall n=385, ICS/LABA n=318, ICS/LABA/LAMA n=67).



*Mini AQLQ - Mini Asthma Quality of Life Questionnaire, range: 1-7 points. score: 7 = no impairment of health-related quality of life, 6 = hardly any impairment, 5 = some impairment, 4 = moderate impairment, 1 = severe impairment



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Responders for Mini AQLQ score at Visit 3 according to minimal clinically important difference (MCID \geq 0.5 points) stratified by prior asthma maintenance treatment.

Prior asthma maintenance treatment	Patients with mean Δ Mini AQLQ score V3-V1 \geq 0.5, n (%)
ICS/LABA* n=318	182 (57.2)
ICS/LABA/LAMA* n=67	34 (50.7)
Overall n=385	216 (56.1)

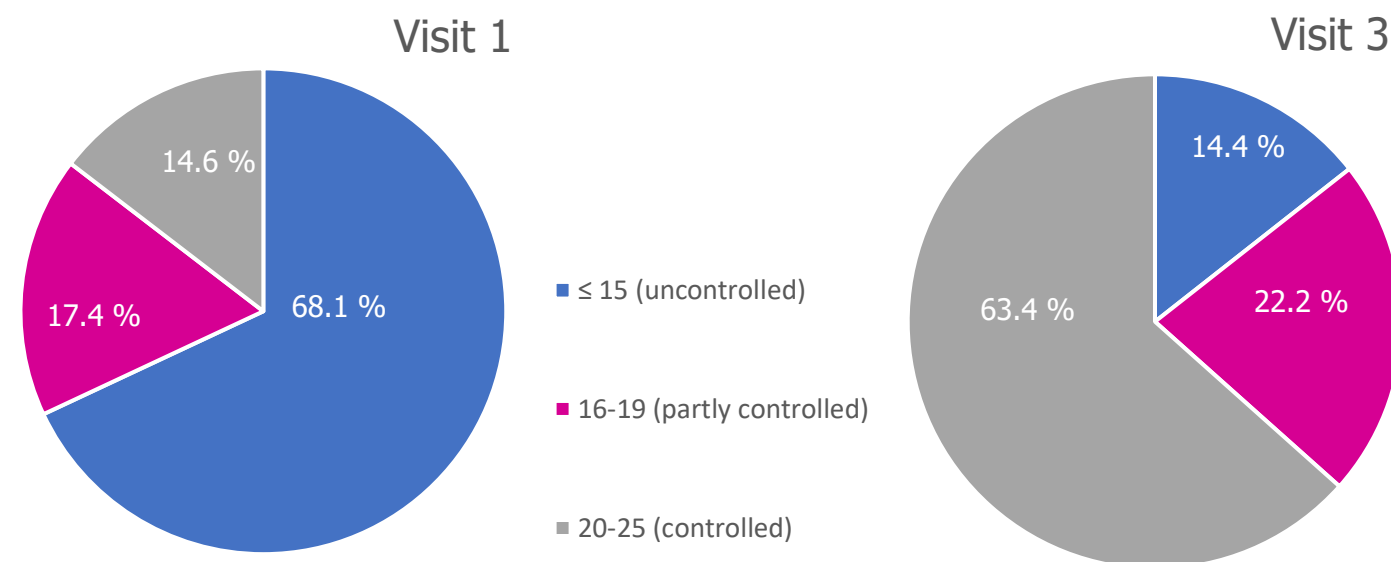
*open or fixed; p=0.3309 (chi-squared test)

Mean ACT score (\pm SD) and the change for ACT score by Mini AQLQ responders at Visit 3.

Mini AQLQ responders at V3	Mean ACT score V1*	Mean ACT score V3	Mean Δ ACT score V3-V1	Paired t-test
Responders n=216	13.7 (4.6)	19.8 (3.7)	6.0 (4.1)	p<0.0001
Non-responders n=169	15.3 (4.7)	16.4 (4.8)	1.1 (3.3)	p<0.0001
Overall n=385	14.4 (4.7)	18.3 (4.5)	3.8 (4.5)	p<0.0001

*5 patients at V1 have no ACT

Total mean Asthma Control Test (ACT) score at Visit 1* and Visit 3 by Mini AQLQ responders at Visit 3 (n=216).



*3 patients at V1 have no ACT



Over 56.1% of patients exceeded the MCID of 0.5 points for the Mini AQLQ and were classified as responders.

MCID for ACT score of 3 points was exceeded in both the responders and the overall population.



Association between the Asthma Control and Health-Related Quality of Life after Six Months of Treatment with Extrafine Single-Inhaler Triple Therapy in TriMaximize Study

Results

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Basic characteristics of the patients in the subgroups.

		Mini AQLQ responders at V3 n=216	Mini AQLQ non-responders at V3 n=169	ACT responders at V3 n=226	ACT non-responders at V3 n=154	ICS/LABA* open or fixed n=318	ICS/LABA/LAMA* open or fixed n=67
Age (years), mean (±SD)		57 (15)	60 (14)	58 (15)	59 (15)	58 (15)	59 (13)
Sex, n (%)	Female	128 (59.3)	98 (58.0)	133 (58.8)	90 (58.4)	184 (57.9)	42 (62.7)
	Male	88 (40.7)	71 (42.0)	93 (41.2)	64 (41.6)	134 (42.1)	25 (37.3)
BMI (kg/m ²), mean (±SD)		29.0 (6.0)	28.9 (6.7)	28.6 (6.1)	29.4 (6.7)	29.1 (6.1)	28.3 (7.5)
Smoking status, n (%)	Former smoker	76 (64.4)	53 (61.6)	76 (65.5)	49 (58.3)	102 (62.6)	27 (65.9)
	Current smoker	42 (35.6)	33 (38.4)	40 (34.5)	35 (41.7)	61 (37.4)	14 (34.1)
Asthma maintenance treatment before switch to efSITT, n (%)	ICS/LABA (open or fixed)	182 (84.3)	136 (80.5)	196 (86.7)	117 (76.0)		
	ICS/LABA/LAM A (open or fixed)	34 (15.7)	33 (19.5)	30 (13.3)	37 (24.0)		

* Asthma maintenance treatment before switch to efSITT.



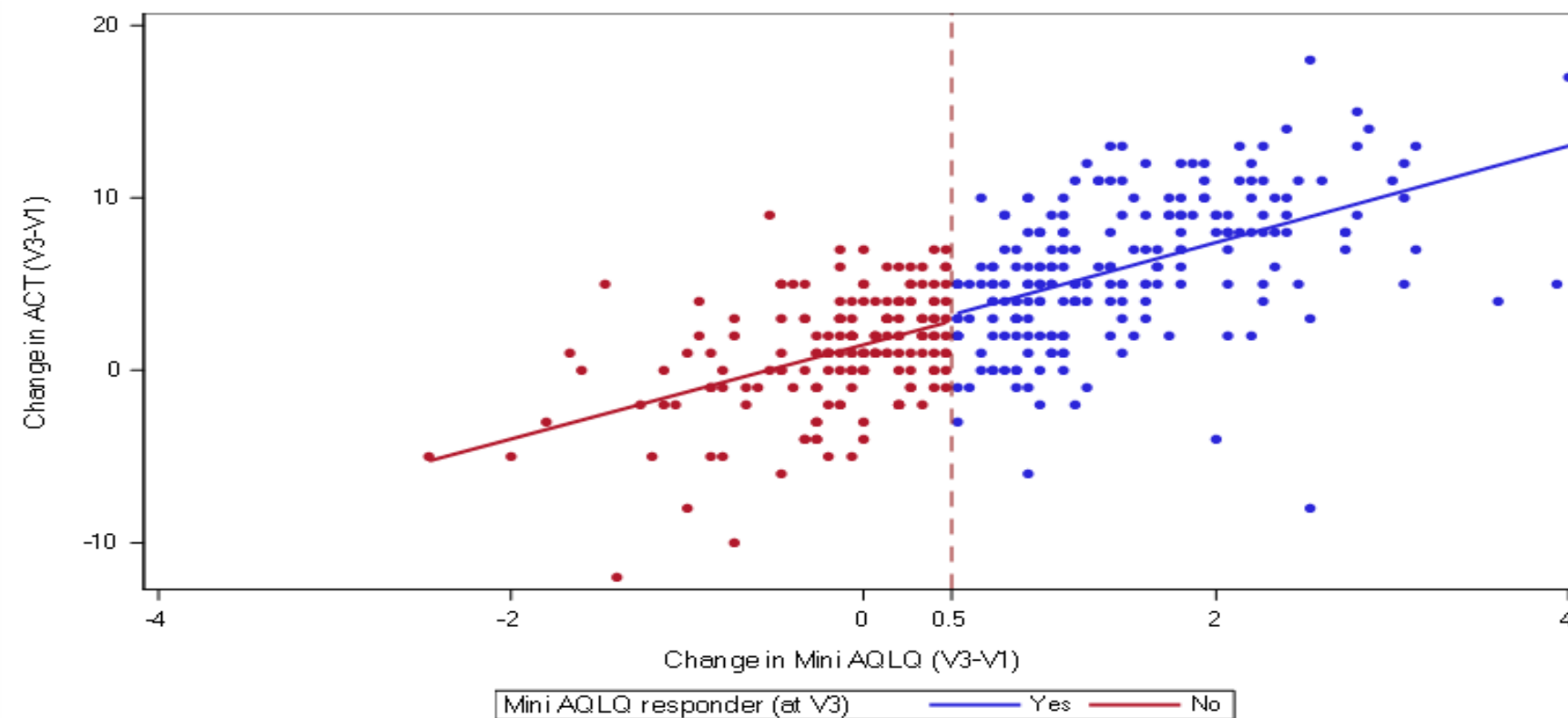
No major variations in the basic characteristics were observed in the subgroups.

Association between the Asthma Control and Health-Related Quality of Life after Six Months of Treatment with Extrafine Single-Inhaler Triple Therapy in TriMaximize Study

Results and conclusion

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Pearson correlation of the Change in ACT score (V3-V1) in Mini AQLQ score (V3-V1).



Subgroup	Correlation	p-value
Mini AQLQ responders at V3 n=213	0.500	<.0001
Mini AQLQ non-responders at V3 n= 167	0.441	<.0001
Overall n=380	0.677	<.0001

Conclusion

Data show that improvement in asthma control is associated with improvement in HRQoL after initiation of efSITT also in a real-world setting.

First Real-World Evidence on High Dose Strength of Extrafine Single-Inhaler Triple Therapy in Asthma Patients after Three Months of Treatment-TriMaximize Study

C. Gessner^{1*}; V. Bogoevska²; D. Nachtigall²; B. Akyildiz²; M.M.Dominique²; A. Wendt²; Carl-Peter Criée³.

¹Specialized Practice for Pulmonary Medicine Leipzig; Leipzig; ²Chiesi GmbH Hamburg, Hamburg; ³Praxis für Innere Medizin und Pneumologie, Northeim.
*Corresponding author: ch.gessner@pneumologe-leipzig.de

TRIMAXIMIZE

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To describe patient characteristics and therapy pathways for patients with a diagnosis of moderate-to-severe asthma who are treated with extrafine BDP/FF/G in real-world practice.

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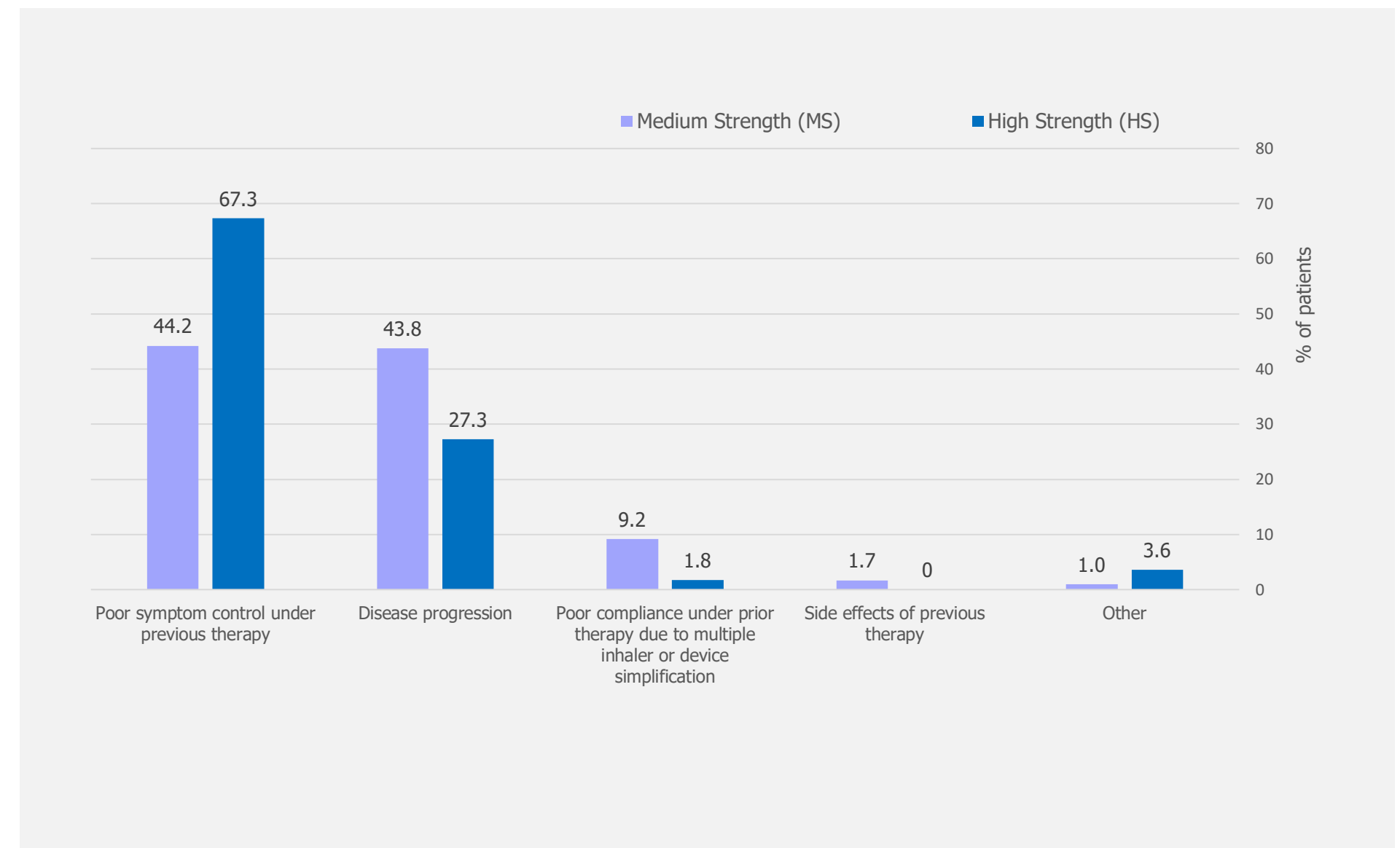
Results

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Baseline characteristics of the patients.

		Medium Strength - MS (87/5/9) n= 584	High Strength - HS (172/5/9) n=55
Age (years), mean (±SD)		59 (15)	54 (17)
Sex, n (%)	Female	367 (62.8)	35 (63.6)
	Male	217 (37.2)	20 (36.4)
BMI (kg/m ²), mean (±SD)		29.3 (8.5)	29.3 (6.0)
Smoking status, n (%)	Former smoker	197 (33.7)	14 (25.5)
	Current smoker	112 (19.2)	11 (20.0)
Pack years, mean (±SD)	Former smoker	19.5 (16.1)	13.0 (14.3)
	Current smoker	26.4 (14.6)	21.7 (16.4)
Time since stopped smoking (years) (±SD)		14.5 (12.5)	17.9 (17.1)
Time since diagnosis at baseline visit, years (±SD)		13.9 (13.9)	15.1 (12.4)
Rate of moderate or severe asthma exacerbations in previous year, mean (±SD)		1.8 (1.4)	1.5 (0.8)
Asthma maintenance treatment before switch to efSITT, n (%)	ICS/LABA (open or fixed)	459 (78.6)	41 (74.5)
	ICS/LABA/LAMA (open or fixed)	125 (21.4)	14 (25.5)

Main reasons for being prescribed BDP/FF/G (MS n=584, HS n=55).

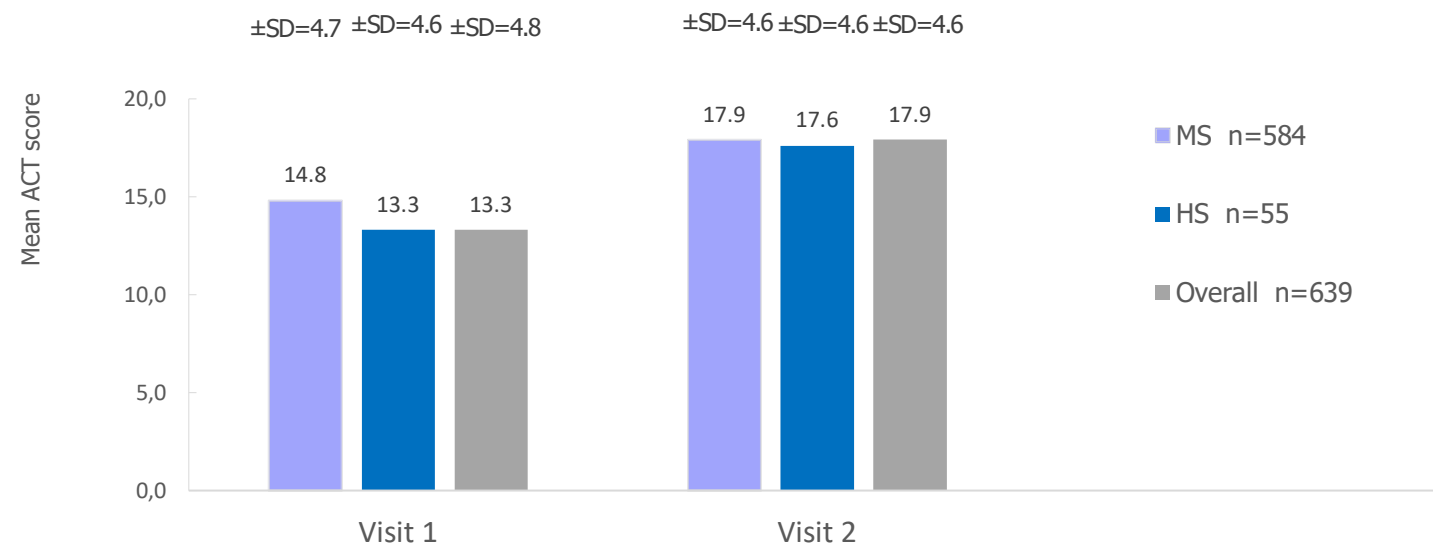


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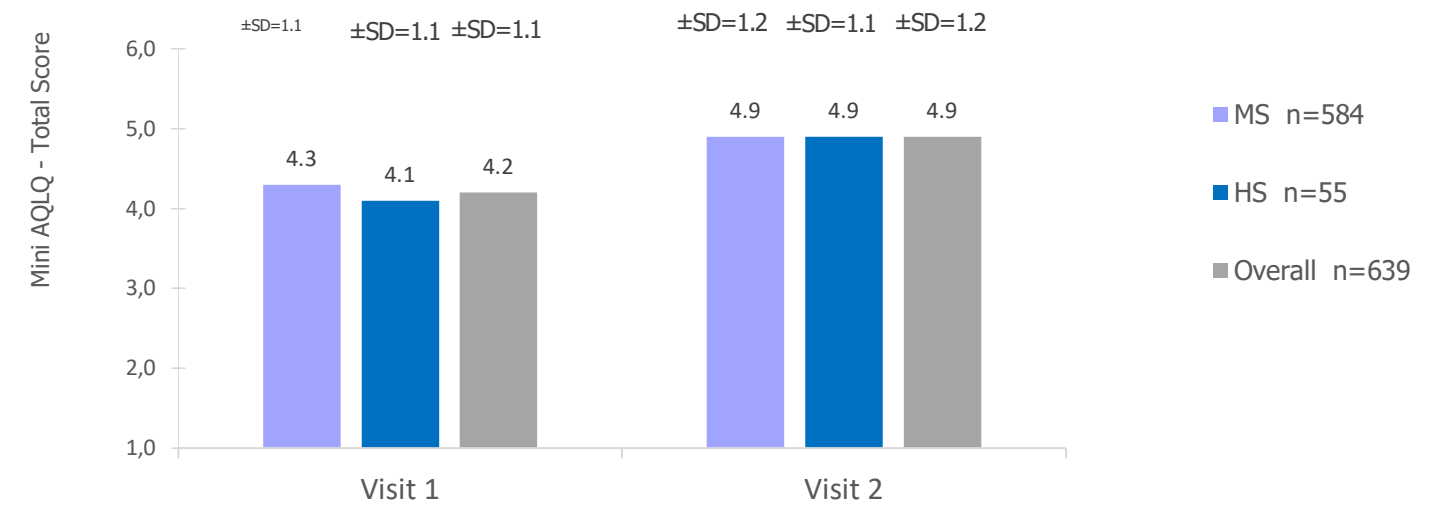
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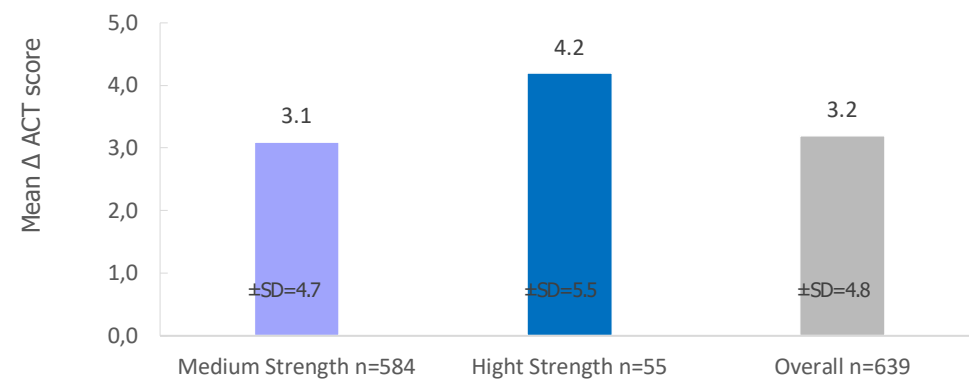
Asthma Control Test (ACT) at Visit 1 and Visit 2.



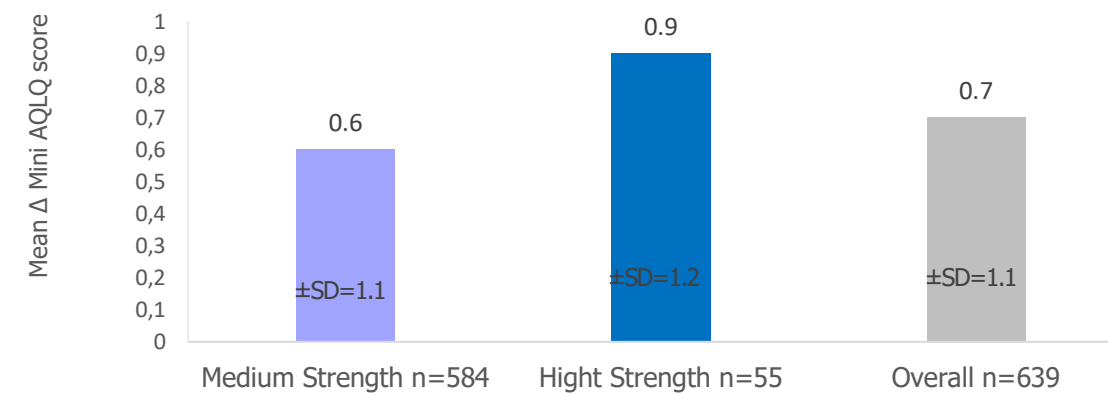
Patient health-related quality of life (HRQoL) according to Mini Asthma Quality of Life Questionnaire (Mini AQLQ)* at Visit 1 and Visit 2.



Mean change of ACT score after three months (V2-V1).



Mean change of Mini AQLQ score after three months (V2-V1).



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

⇒ MCID of 0.5 points for Mini AQLQ was exceeded.



*AQLQ score: 7 = no impairment of health-related quality of life, 6 = hardly any impairment, 5 = some impairment, 4 = moderate impairment, 1 = severe impairment

First Real-World Evidence on High Dose Strength of Extrafine Single-Inhaler Triple Therapy in Asthma Patients after Three Months of Treatment-TriMaximize Study

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Results and Conclusions

Lung function parameters.

	MS (87/5/9) n=584	HS (172/5/9) n=55	Overall n=639
FEV ₁ at baseline (L) (±SD)	1.92 (0.79)	2.17 (0.89)	1.94 (0.80)
Mean change of FEV ₁ (mL)	150 p<0.0001	160 p<0.0016	150 p<0.0001
Mean change of FEV ₁ % of predicted (±SD)	4.73 (12.45) p<0.0001	3.34 (8.62) p<0.0280	4.62 (12.18) p<0.0001
Mean change of RV/TLC (%) (±SD)	- 1.93 (10.50) p<0.0015	- 1.54 (9.94) p<0.3653	- 1.89 (10.43) p<0.0009
Mean change of sRtot (kPa*s) (±SD)	- 0.25 (0.91) p<0.0030	- 0.28 (0.82) p<0.2242	- 0.25 (0.90) p<0.0013

Conclusions

- Both efSITT dose strengths have a significant, rapid-onset effect on asthma control, HRQoL, and lung function in patients with moderate to severe asthma within three months.
- Improvements in disease control and HRQoL exceeded the MCID with effects more pronounced for the high dose strength.

⇒ MCID for FEV₁ of 100 ml was exceeded in both dose strengths.