Impact of extrafine formulation single-inhaler triple therapy on treatment adherence and patient satisfaction in adult asthma – results from the TriMaximize UK study

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Background and Aim

- Asthma affects approximately 7 million people in the UK and is associated with substantial morbidity and mortality.[1]
- The efficacy of an extrafine formulation single-inhaler triple therapy (efSITT) incorporating beclometasone, formoterol and glycopyrronium (BDP/FF/G) in adults with uncontrolled moderate-to-severe asthma has been demonstrated in randomised controlled trials.[2]
- Here we evaluate the impact of efSITT BDP/FF/G use on treatment adherence and patient satisfaction in real-world practice in patients in the UK who enrolled in the TriMaximize study.

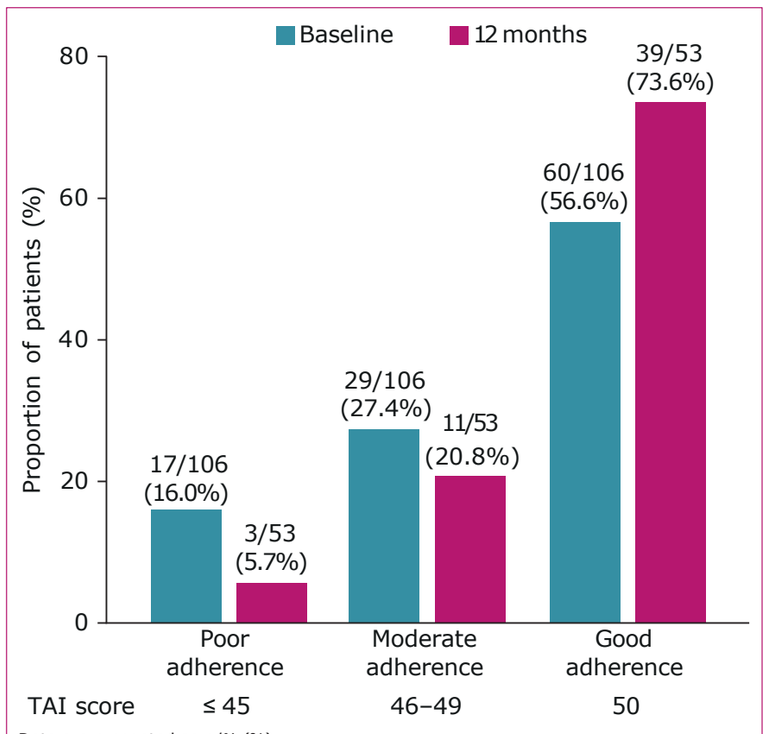
Methods

- TriMaximize is a prospective, non-interventional, multicentre, real-world study that describes patient characteristics and therapy pathways in patients with moderate-to-severe asthma who switched treatment to receive BDP/FF/G.
- The TriMaximize UK (NCT04902573) cohort includes patients enrolled across 20 centres in the UK who are ≥ 18 years of age, have a confirmed diagnosis of asthma with or without concomitant chronic obstructive pulmonary disease, and who have been prescribed treatment with efSITT BDP/FF/G.
- Secondary objectives of TriMaximize included treatment adherence, tolerance and patient satisfaction. Treatment adherence was assessed by the Test of Adherence to Inhalers (TAI).[3] The TAI is a 10-item validated questionnaire designed to detect issues with inhaler use and adherence in everyday practice. A score of ≤ 45 indicates poor adherence; 46–49, moderate adherence; and 50, good adherence. Tolerance and patient-reported satisfaction were assessed by a questionnaire with responses ranging from bad/not satisfied to very good/very satisfied.

Results

- Of 166 patients enrolled, 158 were included in the safety analysis set and 147 were included in the full analysis set. Patient baseline demographic data and characteristics are shown in **Table 1**.
- Immediately before switching to efSITT BDP/FF/G, most patients (72.1%) received treatment with a fixed or free dual inhaled corticosteroid and long-acting beta agonist (ICS/LABA); the remaining patients (27.9%) received fixed or free triple therapy with an ICS/LABA/LAMA.

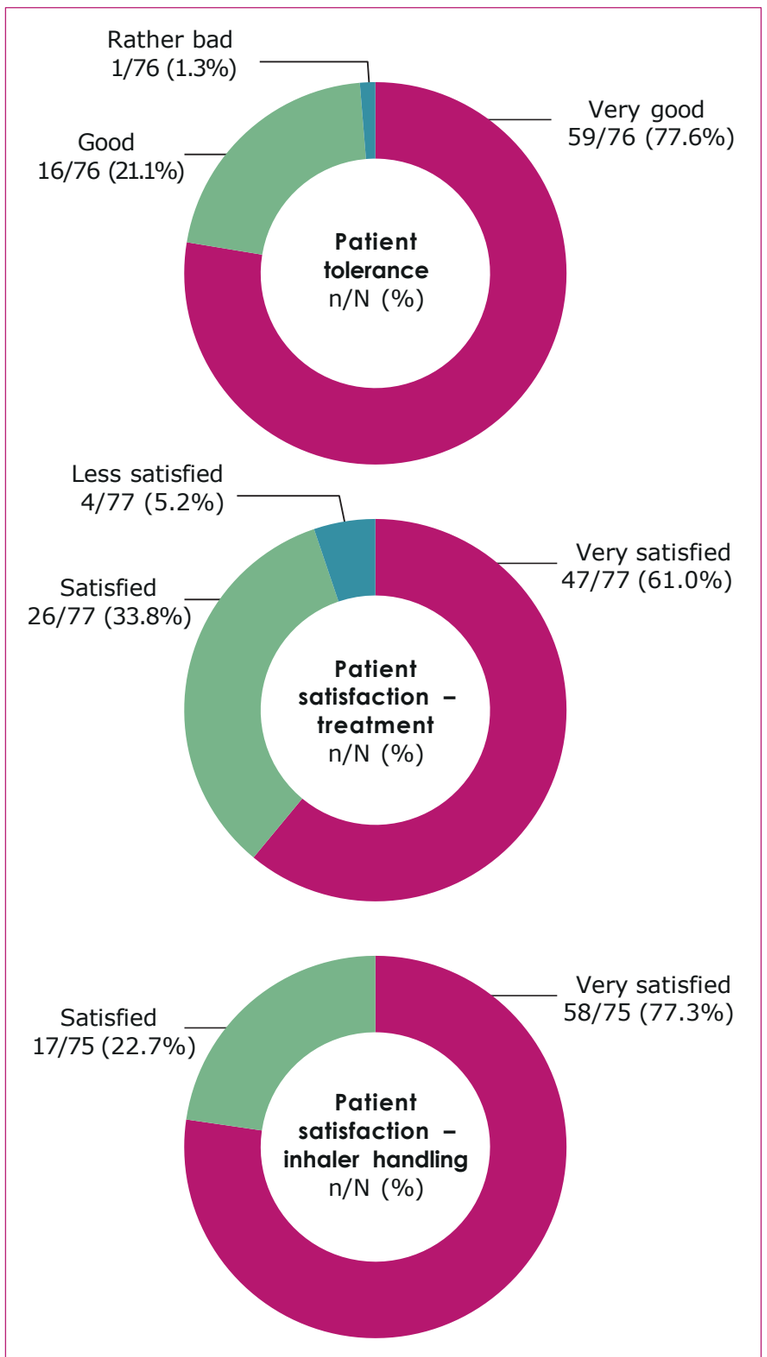
Figure 1. Grouped patient TAI summary scores at baseline and 12 months.



Data are presented as n/N (%).
n/N, number of patients in category/total number of patients; TAI, Test of Adherence to Inhalers.

- The most commonly cited reasons for patients switching to efSITT BDP/FF/G were poor control of symptoms with their previous therapy (74.1%) and disease progression (17.7%).
- Most patients (78.9%) switched to medium-strength BDP/FF/G (87/5/9 mcg), with a smaller proportion (21.1%) switching to high-strength BDP/FF/G (172/5/9 mcg).
  - Owing to the small sample size for high-strength treatment, patients receiving medium- or high-strength treatment were analysed as a single group.
- There was no change in the TAI healthcare professional domain score between baseline and 12 months. At baseline, the mean TAI patient domain summary score was 48.0 points and 56.6% of patients displayed good adherence to treatment (**Figure 1**). At 12 months, there was a significant increase in mean score to 49.2 points ($p = 0.0062$), with 73.6% of patients displaying good adherence.
- Regarding adherence, overall, 78.8% of patients were categorized as TAI responders, achieving a higher adherence category or maintaining good adherence after 12 months when compared to baseline.
- Over 12 months, a total of 94.8% (73/77) and 100.0% (75/75) of patients reported being very satisfied or satisfied with their treatment and with inhaler handling, respectively (**Figure 2**).
- efSITT BDP/FF/G treatment was well tolerated.
  - In total, 289 adverse events were reported in 93 patients (58.9%) during the study (**Table 2**).

Figure 2. Tolerance and patient satisfaction with efSITT BDP/FF/G at 12 months.



BDP/FF/G, beclometasone, formoterol and glycopyrronium; efSITT, extrafine formulation single-inhaler triple therapy; n/N, number of patients in category/total number of patients.

Table 1. Baseline patient demographics and characteristics; full analysis set (N = 147).

Demographic or characteristic		Patients
Mean (SD) age, years		56.3 (16.4)
Sex, n/N (%)	Female	104/147 (70.7)
	Male	43/147 (29.3)
Ethnicity, n/N (%)	White	141/147 (95.9)
	Black	1/147 (0.7)
	Other/mixed	5/147 (3.4)
Most frequent comorbidities, n/N (%)	Anxiety disorders or depression	51/145 (35.2)
	Rhinitis and/or sinusitis	50/143 (35.0)
	Gastroesophageal reflux disease	44/141 (31.2)
	Arterial hypertension	42/144 (29.2)
Concomitant diagnosis of COPD, n/N (%)		29/142 (20.4)
Treatment directly before switching to efSITT BDP/FF/G, n/N (%)	Fixed or free ICS/LABA therapy	106/147 (72.1)
	Fixed or free ICS/LABA/LAMA therapy	41/147 (27.9)
Systemic corticosteroid use in the past 12 months, n/N (%)		110/147 (74.8)
Smoking status, n/N (%)	Never	69/147 (46.9)
	Current	23/147 (15.6)
	Former	55/147 (37.4)

BDP/FF/G, beclometasone, formoterol and glycopyrronium; COPD, chronic obstructive pulmonary disease; efSITT, extrafine formulation single-inhaler triple therapy; ICS/LABA, inhaled corticosteroid and long-acting beta agonist; ICS/LABA/LAMA, inhaled corticosteroid, long-acting beta agonist and long-acting muscarinic antagonist; n/N, number of patients in category/total number of patients; SD, standard deviation.

Table 2. Summary of AEs; safety analysis set (N = 158).

Safety analysis set	Patients, n (%)
Any AE	93 (58.9)
Respiratory, thoracic and mediastinal disorders[a]	54 (34.2)
Asthma	46 (29.1)
Dyspnoea	7 (4.4)
Cough	6 (3.8)
Infections and infestations[a]	31 (19.6)
Lower respiratory tract infection	10 (6.3)
Infective exacerbation of asthma	7 (4.4)
Nervous system disorders[a]	10 (6.3)
Headache	6 (3.8)
Any SAE	15 (9.5)
Any ADR	29 (18.4)
Any fatal AE	1(0.6)[b]

[a]Only events that occurred in ≥ 3% of patients are shown. [b]Considered not related to treatment. ADR, adverse drug reaction; AE, adverse event; SAE, serious adverse event.

Summary and Conclusions

- Patients treated with efSITT BDP/FF/G had a significant improvement in treatment adherence between baseline and 12 months.
- Overall, efSITT BDP/FF/G was well tolerated and a majority of patients were very satisfied with both their treatment and the handling features of their inhaler after 12 months.

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Disclosures

Jennifer Richards and Adam Rostron are employees of Chiesi Ltd. Richard E K Russell has received fees for conducting the study.

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