Critical error rates with the ELLIPTA inhaler compared with other dry-powder inhalers in patients with COPD: an open-label, low-intervention clinical study


Aims

Similarities of inhalation characteristics (ICS, long-acting β2-agonists (SABA), and long-acting muscarinic antagonists (LAMA)) are recommended for chronic obstructive pulmonary disease (COPD) management.

Errors in inhaler use, particularly critical errors (critical errors leading to or significantly reduced medication being inhaled), may reduce treatment efficacy.

The ELLIPTA inhaler, a dry-powder inhaler (DPI) able to deliver the ICS/LAMA/LABA regimen fluticasone propionate/indacaterol (FF/VI) in a single dose, is associated with fewer critical errors than other commonly used DPIs and multidose inhalers.

We conducted the current study to assess critical error rates with the ELLIPTA inhaler versus other commonly used DPIs, alone and in combination after and before error correction, which originated from a HCP in a low-intervention setting.

Methods

This open-label, low-intervention clinical study was carried out in 13 centers in the Netherlands (6), the United Kingdom (5) and France (2) from June 2017 to March 2018.

Enrolled patients were ≥ 18 years of age with a physician's diagnosis of COPD and had received one of the following DPIs or inhaler combinations: ELLIPTA (V1) or HandiHaler (HCP) for ≥ 3 months prior to inclusion:

- ELLIPTA FF/VI (100/500 μg) or ELLIPTA (62.5/25 μg)
- Turbuhaler budesonide/formoterol (TURBUHALER) (80/4.5 μg)
- Diskus fluticasone propionate/salmeterol (FP/SAL) (500/50 μg)
- Breather Indacaterol/Glycopyrronium (INH/BID) (150/24.3 μg)
- LAMA-only inhaler (HandiHaler [TIO] 320 μg or ELLIPTA [MBC] 62.5 μg).

The study comprised two visits (V1 and V2) (Figure 1).

The primary endpoint was the percentage of patients making a critical error at V1 or V2 for each DPI tested (prior to retraining).

The key secondary endpoint was the proportion of patients making a critical error at V1 or V2 for each single DPI tested (6 weeks after retraining, if needed).

Single DPIs and DPI combinations were assessed for each endpoint analysis. Analyses were conducted from the perspective of the primary investigator (ELLIPTA, LAMAB, or LAMA-only inhaler 4 using two DPIs).

Correct use and inhaler errors were assessed against a checklist for each DPI. Checklists were based on the steps outlined in the appropriate patient information leaflet.

Primary and secondary endpoints were analyzed using a logistic regression model, with treatment options as fixed effects. Post-hoc sensitivity analyses were performed as time on DPI was confounded with DPI type, patients were likely to have used ELLIPTA less time than other DPIs.

All odds ratios (ORs) reported are from post-hoc sensitivity analyses due to the confounding issue described.

Results

Patient demographics and clinical characteristics

- Overall, 461 patients were screened and 459 were enrolled into one of nine DPI cohorts
- Demographic and clinical characteristics were similar across DPI cohorts, with a mean age of 67.3 years (standard deviation 8.3), 54% of the IT was female.

Critical errors with the primary inhaler at V1

- For the ELLIPTA inhaler, the number of patients making ≥ 1 critical error at V1 was 5/56 (10%), with ELLIPTA FF/VI, 25/30 (80%) with ELLIPTA Disks, and 15/58 (26%) with DISKUS FF/VI (Figure 2a).
- The odds of a patient making ≥ 1 critical error was 5.04 times greater with Turbuhaler BUD/FOR (95% confidence interval [CI]: 1.93–16.1; p=0.001) and 2.38 times greater with DISKUS FF/VI (95% CI: 1.00–6.84; p=0.050) than with ELLIPTA FF/VI (Figure 2a).
- For the LAMA and LAMA-LABA inhalers, the number of patients making ≥ 1 critical error at V1 was 3/55 (5%) with ELLIPTA UMEC/LAMA, 13/93 (34%) with HandiHaler TIO, and 15/54 (29%) with Breather IND/GLY with GLY (95% CI: 1.42–12.18; p=0.009) than with ELLIPTA UMEC/LABA (Figure 2b).

Addition of a LAMA inhaler had minimal effect on critical error rates with the primary inhaler at V1. The number of patients making ≥ 1 critical error at V1 with FF/VI was 1/20 (5%) with HandiHaler TIO, and 2/13 (15%) with Breather IND/GLY with GLY (95% CI: 1.18–55.94; p=0.128) than with ELLIPTA UMEC/LABA.

All critical errors (95%) were shared, with the exception of two critical errors noted on ELLIPTA and HandiHaler.

Conclusions

The ELLIPTA inhaler compared with other dry-powder inhalers, particularly with the FF/VI combination, may reduce critical errors over the study period.

A more detailed analysis of critical errors with the ELLIPTA inhaler versus other DPIs is needed to understand the impact.

References

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