Potential taste disturbance is largely mild and diminishes on continuing treatment with levofloxacin inhaled solution (LIS) in cystic fibrosis (CF) patients

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Introduction

Pivotal trials and clinical practice have demonstrated and confirmed the efficacy of LIS in adults with CF. Moreover, the overall tolerability profile of LIS was similar to placebo and tobramycin inhaled solution (TIS) in controlled trials. Dysgeusia was more common in LIS-treated patients than controls. This analysis reviews dysgeusia data from an active control trial and its open label extension (OLE), in the context of the wider clinical trial programme.

Methods

Patients completed a placebo controlled study (*Flume et al, J Cyst Fibros 2016;15(4):495-502*) or a phase III non-inferiority study comparing LIS and TIS over three 28-day on/off cycles (NCT01270347; *Elborn et al, J Cyst Fibros 2015;14(4):507-514*) including a 6-month OLE for three further cycles (*Elborn et al, J Cyst Fibros 2016; 15(5):634-640*). Safety was assessed at each study visit.

Results

- Dysgeusia was reported by 34.7% of LIS-treated patients in the placebo-controlled study, 25.3 % in a study where TIS was the active control and 9.1% in the OLE. Most reports of dysgeusia occurred during the 'on-treatment period'.
- In patients treated with LIS both in the original randomised study and in the extension study (LIS/LIS), 9/56 (16.1%) reported dysgeusia during the randomized phase and 1/56 (1.8%) during the extension (Fig. 1).
- Events were mostly mild to moderate in severity (Fig. 2). Very few subjects stopped treatment because of dysgeusia in the placebo-controlled trial (2.3%) or in the active controlled trial (1.1%).
- Importantly, in the 6-month OLE, in which all patients had already received TIS or LIS, no patients stopped treatment because of dysgeusia.

Figure 1. Proportion of patients (%) in OLE study first experiencing dysgeusia. Data are reported for the overall group and for patients stratified based on treatment received during randomized phase and OLE

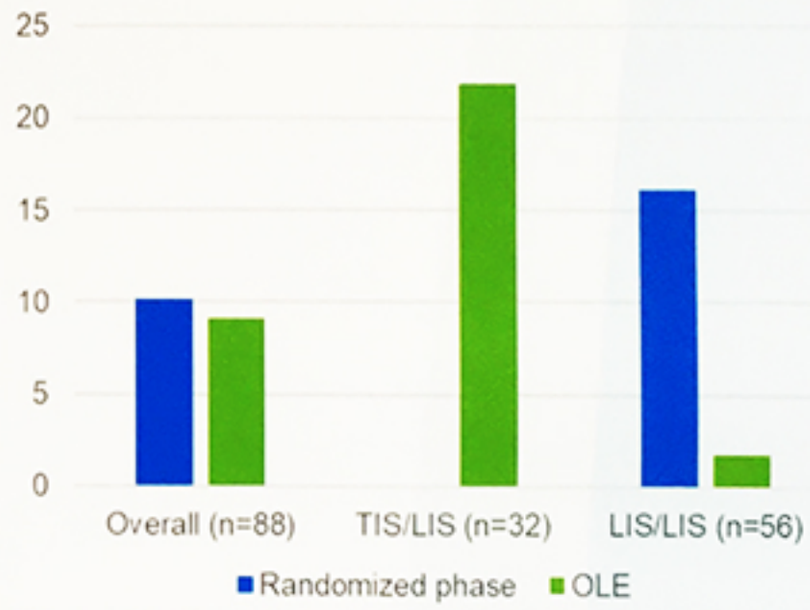
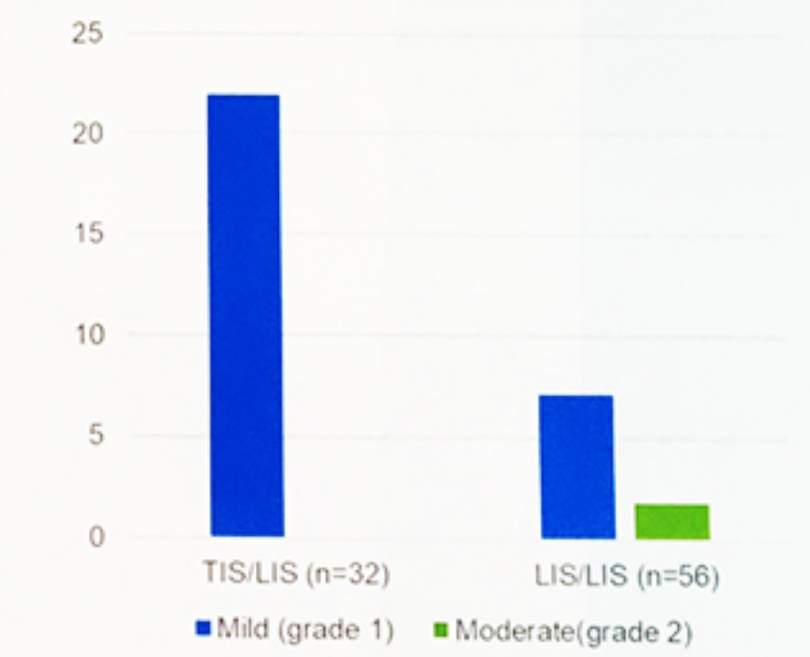


Figure 2. Severity of dysgeusia events in patients participating to OLE study stratified by treatment received during randomized phase and OLE



Conclusion

Dysgeusia may be associated with LIS, but subjects typically rate it as only mild-to-moderate in severity, and rarely stop medication because of it.

Rates of dysgeusia reduced after six months of LIS treatment, suggesting a short-lived effect rather than a long-term taste impairment.

Abbreviations

LIS = levofloxacin inhaled solution
OLE = open label extension
TIS = tobramycin inhaled solution

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