

P261 TIOPIPIUM SAFETY AND PERFORMANCE IN RESPIMAT® (TIOPIPIUM™): SAFETY AND EFFICACY IN PATIENTS NAÏVE TO TREATMENT WITH ANTICHOLINERGICS

¹R Wise, ²P Calverley, ³R Dahl, ⁴D Dusser, ⁵N Metzdorf, ⁶A Mueller, ⁷A Fowler, ⁸A Anzueto. ¹Johns Hopkins University School of Medicine, Baltimore, MD, USA; ²Institute of Ageing and Chronic Disease, University of Liverpool, Liverpool, UK; ³Odense University Hospital, Odense, Denmark; ⁴Service de Pneumologie Hôpital Cochin, AP-HP, Université Paris Descartes, Sorbonne Paris Cité, Paris, France; ⁵Boehringer Ingelheim Pharma GmbH and Co KG, Ingelheim, Germany; ⁶Boehringer Ingelheim Pharma GmbH and Co KG, Biberach, Germany; ⁷Boehringer Ingelheim Pharma Ltd, Bracknell, UK; ⁸Pulmonary Critical Care Center, San Antonio, TX, USA

10.1136/thoraxjnl-2014-206260.389

Introduction The TIOSPIR™ trial showed similar safety and exacerbation efficacy profiles for tiotropium Respimat® and HandiHaler® in patients with chronic obstructive pulmonary disease (COPD). We present here the results for patients who were naïve to anticholinergic treatment at baseline.

Methods TIOSPIR™ (n = 17,135), a 2–3 year, randomised, double-blind, parallel-group, event-driven trial, compared safety and efficacy of once-daily tiotropium Respimat® 5 and 2.5 µg with HandiHaler® 18 µg in patients with COPD. Primary endpoints were time to death (noninferiority of Respimat® 5 or 2.5 µg versus HandiHaler®) and time to first COPD exacerbation (superiority of Respimat® 5 µg versus HandiHaler®). Safety, including cardiovascular safety, was assessed.

Results Overall, 6966 patients from TIOSPIR™, naïve to anticholinergic treatment at baseline, were randomised and treated (n = 2345, n = 2312 and n = 2309 for tiotropium Respimat® 2.5 and 5 µg and HandiHaler® 18 µg). There was similar risk of death (vital status follow up) (measured as time to death) for the Respimat® groups versus HandiHaler® (Respimat® 5 µg: hazard ratio [HR], 0.93; 95% confidence interval [CI], 0.75–1.17; Respimat® 2.5 µg: HR, 1.05; 95% CI, 0.84–1.30) with similar results for the on-treatment sensitivity analysis (Respimat® 5 µg: HR, 0.91; 95% CI, 0.71–1.17; Respimat® 2.5 µg: HR, 1.11; 95% CI, 0.87–1.40). Risk of exacerbation was also similar for the Respimat® groups versus HandiHaler® (measured as time to first exacerbation) (Respimat® 5 µg: HR, 0.99; 95% CI, 0.90–1.08; Respimat® 2.5 µg: HR, 1.04; 95% CI, 0.95–1.14). Risk of major adverse cardiovascular event (MACE) or fatal MACE were similar for the Respimat® groups versus HandiHaler® (MACE: Respimat® 5 µg: HR, 1.20; 95% CI, 0.88–1.63; Respimat® 2.5 µg: HR, 1.11; 95% CI, 0.81–1.51; fatal MACE: Respimat® 5 µg: HR, 1.14; 95% CI, 0.75–1.71, Respimat® 2.5 µg: HR, 1.12; 95% CI, 0.75–1.69).

Conclusions Analogous to the global analysis, patients naïve to anticholinergic treatment and treated with tiotropium Respimat® 2.5 or 5 µg or HandiHaler® in the TIOSPIR™ trial exhibited similar safety and exacerbation efficacy profiles.

P262 TIOPIPIUM SAFETY AND PERFORMANCE IN RESPIMAT® (TIOPIPIUM™): SAFETY AND EFFICACY IN PATIENTS WITH TIOPIPIUM HANDIHALER® USE AT BASELINE

¹P Calverley, ²A Anzueto, ³R Dahl, ⁴A Mueller, ⁵A Fowler, ⁶N Metzdorf, ⁷R Wise, ⁸D Dusser. ¹Institute of Ageing and Chronic Disease, University of Liverpool, Liverpool, UK; ²Pulmonary Critical Care Center, San Antonio, TX, USA; ³Odense University Hospital, Odense, Denmark; ⁴Boehringer Ingelheim Pharma GmbH and Co KG, Biberach, Germany; ⁵Boehringer Ingelheim Pharma Ltd, Bracknell, UK; ⁶Boehringer Ingelheim Pharma GmbH and Co KG, Ingelheim, Germany; ⁷Johns Hopkins University School of

Medicine, Baltimore, MD, USA; ⁸Service de Pneumologie Hôpital Cochin, AP-HP, Université Paris Descartes, Sorbonne Paris Cité, Paris, France

10.1136/thoraxjnl-2014-206260.390

Introduction The TIOSPIR™ trial showed that tiotropium Respimat® and HandiHaler® have similar safety and exacerbation efficacy profiles in patients with chronic obstructive pulmonary disease (COPD). We present here results for patients from the United States (US) using tiotropium HandiHaler® at baseline.

Methods TIOSPIR™ (n = 17,135), a 2–3 year, randomised, double-blind, parallel-group, event-driven trial, compared safety and efficacy of once-daily tiotropium Respimat® 5 and 2.5 µg with once-daily HandiHaler® 18 µg in patients with COPD. Primary endpoints were time to death and time to first COPD exacerbation. Safety, including cardiovascular safety, was assessed. Tiotropium Respimat® was unavailable in the US (baseline tiotropium HandiHaler® use only), therefore this subgroup was analysed.

Results Overall, 1779 patients from TIOSPIR™ treated with tiotropium HandiHaler® 18 µg at baseline in the US were randomised and treated (n = 572, n = 602 and n = 605 for tiotropium Respimat® 2.5 and 5 µg and HandiHaler® 18 µg). A numerically lower time to death was observed for patients within the Respimat® groups versus HandiHaler® (vital status follow up: Respimat® 5 µg: hazard ratio [HR], 0.77; 95% confidence interval [CI], 0.53–1.12; Respimat® 2.5 µg: HR, 0.76; 95% CI, 0.52–1.12). Risk of major adverse cardiovascular event (MACE) and fatal MACE was numerically lower for the Respimat® groups versus HandiHaler® (MACE: Respimat® 5 µg: HR, 0.69; 95% CI, 0.41–1.18; Respimat® 2.5 µg: HR, 0.83; 95% CI, 0.50–1.39; fatal MACE: HR, 0.60; 95% CI, 0.26–1.37; Respimat® 2.5 µg: HR, 0.42; 95% CI, 0.16–1.09). Overall incidence of a fatal event (on-treatment) was lower in the Respimat® groups versus HandiHaler® (Respimat® 5 µg: HR, 0.60; 95% CI, 0.39–0.92; Respimat® 2.5 µg: HR, 0.67; 95% CI, 0.44–1.02). Time to first exacerbation was similar across groups (Respimat® 5 µg versus HandiHaler®: HR, 0.94; 95% CI, 0.82–1.08).

Conclusions Patients treated with tiotropium HandiHaler® 18 µg at baseline, and who were randomised and subsequently received tiotropium Respimat® 2.5 or 5 µg, had a similar risk of exacerbation as patients who continued to be treated with tiotropium HandiHaler® 18 µg. In this subgroup of patients, all-cause mortality was similar between tiotropium Respimat® and HandiHaler® 18 µg.

Abstracts M263 to M272 are found on page A218–A223.

ILD: diagnosis, co-morbidities and treatment

P273 ASSESSMENT OF LUNG MICROSTRUCTURE IN INTERSTITIAL LUNG DISEASE WITH HYPERPOLARISED GAS MRI

¹NJ Stewart, ¹G Norquay, ¹J Parra-Robles, ¹H Marshall, ¹G Leung, ²PS Murphy, ³RF Schulte, ¹CA Elliot, ¹R Condliffe, ⁴CG Billings, ⁴I Smith, ¹PD Griffiths, ⁵J Wolber, ¹MKB Whyte, ¹DG Kiely, ¹JM Wild. ¹University of Sheffield, Sheffield, UK; ²GlaxoSmithKline, Brentford, UK; ³GE Global Research, Garching, Germany; ⁴Royal Hallamshire Hospital, Sheffield, UK; ⁵GE Healthcare, Amersham, UK

10.1136/thoraxjnl-2014-206260.391

Introduction and objectives Magnetic resonance (MR) imaging of the hyperpolarised noble gases ³He and ¹²⁹Xe provides