Assessing the Validity of Netherlands Linked Routine Healthcare Resource Utilisation Data in the Investigation of Single-Inhaler Triple Therapy Effectiveness (INTREPID Trial)

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Numbere B,[1] Smits E,[2] Holthuis E,[2] Lu Y,[1,3] Fry M,[4] Compton C,[1] Ismaila AS,[5,6] Rothnie KJ[1]

[1]Value Evidence and Outcomes, R&D Global Medical, GSK, Brentford, UK; [2]PHARMO Institute for Drugs Outcomes Research, the Netherlands; [3]Department of Epidemiology, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA; [4]Value Evidence and Outcomes, R&D Global Medical, GSK, Stevenage, UK; [5]Value Evidence and Outcomes, R&D Global Medical, GSK, Collegeville, PA, USA; [6]Department of Health Research Methods, Evidence and Impact, McMaster University, Hamilton, ON, Canada

Background

The pragmatic INTREPID study assessed the effectiveness of single-inhaler triple therapy with fluticasone furoate/umeclidinium/vilanterol versus multiple-inhaler triple therapy in the treatment of chronic obstructive pulmonary disease (COPD)[1]

Real-world pragmatic trials are important for evaluating effectiveness of a drug in usual clinical practice and can complement data derived from phase III randomised controlled trials

An exploratory outcome of the INTREPID study was to assess COPD-related healthcare resource use (HCRU) among patients during the treatment phase of the trial

Aims

The aim of this study was to summarise HCRU for INTREPID patients during their baseline and treatment phase, and to assess the validity and practicality of future pragmatic trials using external database-derived data as a method to ascertain HCRU outcomes

Methods

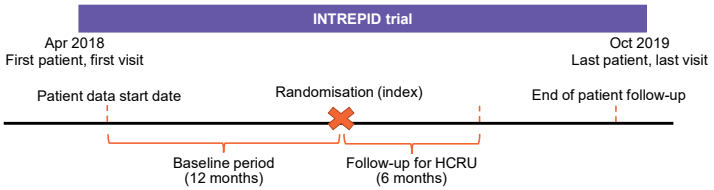
A cohort study of patients with COPD included in the INTREPID trial who consented to linkage to the Hospital Database of the PHARMO Database Network in the Netherlands. Patients' INTREPID study start date was defined as the index date

HCRU was assessed in the 12 months prior to index (baseline period) and for up to 6 months following index (**Figure 1**)

- Patients were followed until their INTREPID study end date, date of death, database exit date or last database collection date (31 December 2019), whichever was earliest

All patients were required to have 12 months of baseline data available. Patient characteristics (sex, age, year of INTREPID study start and length of follow-up [months]) were described at index

Figure 1. Study design



HCRU, healthcare resource utilisation.

Results

Patient characteristics

INTREPID enrolled 588 patients from the Netherlands; 211 patients consented and had a 12-month baseline period, of which 203 patients were successfully linked with PHARMO's Hospital Database and were included in the study cohort for HCRU analysis (**Table 1**)

Table 1. Patient characteristics

	Total (N=203)
Age, years, mean (SD)	66 (7)
Female, n (%)	107 (53)
Year of index date, n (%)	
2018	83 (41)
2019	120 (59)
Follow-up from index, months, n (%)	
5	68 (33)
6	135 (67)

SD, standard deviation.

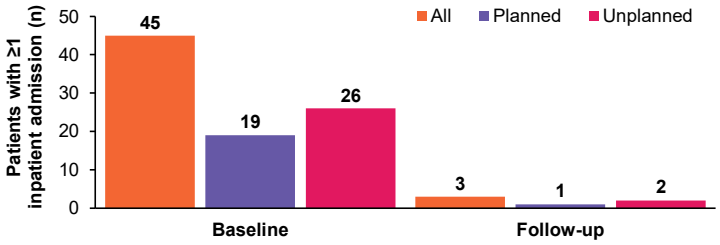
COPD-related inpatient admissions

During baseline, 45 patients had ≥1 COPD-related inpatient admission, with a mean frequency of hospitalisation of 1 (standard deviation [SD]: 0) and during follow-up, 3 patients had ≥1 COPD-related inpatient admission with a mean frequency of hospitalisation of 2 (SD: 2) (**Figure 2**)

Overall, 26 patients had ≥1 unplanned COPD-related inpatient admission with a mean frequency of hospitalisation of 1 (SD: 0) during baseline, and 2 patients had ≥1 unplanned COPD-related inpatient admission with a mean frequency of hospitalisation of 3 (SD: 1) during follow-up (**Figure 2**)

Mean (SD) length of stay for COPD-related inpatient admissions was 7 (4) days and 14 (14) days during baseline and follow-up, respectively

Figure 2. COPD-related inpatient admissions



COPD, chronic obstructive pulmonary disease.

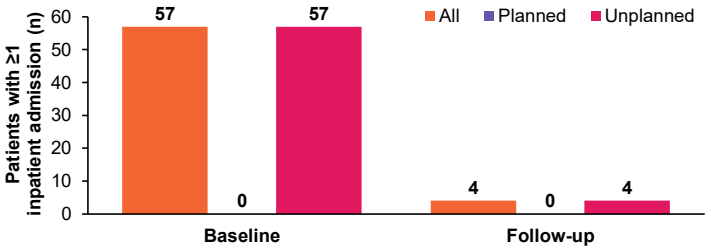
All-cause inpatient admissions

During baseline, 57 patients had ≥1 all-cause inpatient admission, with a mean frequency of hospitalisation of 1 (SD: 0). Of these, 100% were unplanned (**Figure 3**)

During follow-up, 4 patients had ≥1 all-cause inpatient admission, with a mean frequency of hospitalisation of 2 (SD: 1). Of these, 100% were unplanned (**Figure 3**)

Mean (SD) length of stay for all-cause inpatient admissions was 6 (4) days and 11 (13) days during baseline and follow-up, respectively

Figure 3. All-cause inpatient admissions



Intensive care unit (ICU) admissions

During baseline, 2 patients (1%) were hospitalised in the ICU, both COPD-related. Mean (SD) length of stay in the ICU was 15 (4) days. During follow-up, no ICU admission was recorded

Limitations

Although not the objective of this study, a comparison of HCRU between baseline and follow-up cannot be made due to the difference in length of time period

Monitoring of patients may be superior during the study compared with the baseline period

The PHARMO Database network contains data from primary and secondary healthcare settings, but only the inpatient secondary care settings were captured by this dataset. Therefore, this only provides a summary of HCRU for patients in the secondary care inpatient setting

The small sample sizes from INTREPID due to attrition meant the validity of data within certain hospital settings, such as critical care, could not be fully explored through summary measures

Conclusions

Linked HCRU data were available for INTREPID patients with greater granularity than data generally available from prospectively collected patient recall of HCRU in pragmatic studies

Future studies should consider using linked routine hospital data alongside prospectively collected data in pragmatic trials in routine practice in the Netherlands

Disclosures

The authors declare the following real or perceived conflicts of interest during the last three years in relation to this presentation:

- MF, CC, ASI and KJR are employees of GSK and/or hold stocks/shares in GSK
- ASI is also a part-time member of the McMaster University faculty
- BN is an employee of CY Partners Recruitment Ltd and on assignment at GSK as a Complementary Worker
- YL is a university worker at GSK and a graduate researcher at University of North Carolina in Chapel Hill
- ES and EH are employed by PHARMO Institute for Drug Outcomes Research, an independent research institute that performs financially supported studies for government and related healthcare authorities and pharmaceutical companies

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Author email address: kieran.j.rothnie@gsk.com

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