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Real world effects of COPD medications: a cohort study with validation against results from randomised controlled trials

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ABSTRACT   Real-world data provide the potential for generating evidence on drug treatment effects in groups excluded from trials, but rigorous, validated methodology for doing so is lacking. We investigated whether non-interventional methods applied to real-world data could reproduce results from the landmark TORCH COPD trial.

We performed a historical cohort study (2000–2017) of COPD drug treatment effects in the UK Clinical Practice Research Datalink (CPRD). Two control groups were selected from CPRD by applying TORCH inclusion/exclusion criteria and 1:1 matching to TORCH participants, as follows. Control group 1: people with COPD not prescribed fluticasone propionate (FP)-salmeterol (SAL); control group 2: people with COPD prescribed SAL only. FP-SAL exposed groups were then selected from CPRD by propensity score matching to each control group. Outcomes studied were COPD exacerbations, death from any cause and pneumonia.

2652 FP-SAL exposed people were propensity score matched to 2652 FP-SAL unexposed people while 991 FP-SAL exposed people were propensity score matched to 991 SAL exposed people. Exacerbation rate ratio was comparable to TORCH for FP-SAL *versus* SAL (0.85, 95% CI 0.74–0.97 *versus* 0.88, 0.81–0.95) but not for FP-SAL *versus* no FP-SAL (1.30, 1.19–1.42 *versus* 0.75, 0.69–0.81). In addition, active comparator results were consistent with TORCH for mortality (hazard ratio 0.93, 0.65–1.32 *versus* 0.93, 0.77–1.13) and pneumonia (risk ratio 1.39, 1.04–1.87 *versus* 1.47, 1.25–1.73).

We obtained very similar results to the TORCH trial for active comparator analyses, but were unable to reproduce placebo-controlled results. Application of these validated methods for active comparator analyses to groups excluded from randomised controlled trials provides a practical way for contributing to the evidence base and supporting COPD treatment decisions.