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Clinical Trial Paper

A two-year evaluation of the 'real life' impact of COPD on patients in Germany: The DACCORD observational study

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ABSTRACT

Introduction: DACCORD is an observational, non-interventional study being conducted in German primary and secondary care centres. The study aims to describe the impact of disease (including exacerbations) and treatments over 2 years on 'real-life' patients with chronic obstructive pulmonary disease (COPD).

Materials and methods: Patients had a clinical and spirometry diagnosis of COPD, were aged ≥40 years and, on recruitment, were initiating or changing COPD maintenance medication. The only exclusion criteria were asthma and randomised clinical trial participation. Exacerbations data were collected every 3 months. COPD medication, COPD Assessment Test (CAT) and forced expiratory volume in 1 s (FEV_1) were recorded at baseline and after 1 and 2 years.

Results: A total of 6122 patients were recruited, 3137 (51.2%) of whom completed the 2-year visit. The mean age of these patients was 65.6 years, 59% were male, 69% had mild or moderate airflow limitation, and their mean COPD Assessment Test (CAT) total score was 20.3. Overall, there was a trend towards decreasing COPD exacerbation rates over the 2-year follow-up period, with rates of 0.390 during Year 1 and 0.347 during Year 2. Rates were lower in patients with no exacerbation during the 6 months prior to entry (0.263 and 0.251 during Years 1 and 2, respectively), with 51.6% of patients having no exacerbation during the 6 months prior to entry and over the 2-year follow-up. Approximately 50% of the overall population experienced a clinically relevant improvement from baseline in CAT total score at Year 1 and 2. When assessed by treatment class (or classes), persistence to medication was high (77.8% in Year 1 and 71.4% in Year 2).

Conclusions: Overall, the 2-year follow-up data from DACCORD suggest that for most patients with COPD exacerbations are a rare event. For the majority of patients, the focus should be on managing symptoms, and the impact that these symptoms have on their daily lives. Even for those patients who do exacerbate, although prevention of exacerbations is an important factor, management of symptoms should be a key consideration. DACCORD also suggests that COPD disease progression is not inevitable – providing patients are receiving pharmacological treatment.

1. Introduction

Chronic obstructive pulmonary disease (COPD) is generally considered to be a progressive disease, with patients experiencing a gradual loss in lung function together with increasing symptoms [1]. The evaluation of the severity of COPD should take both current

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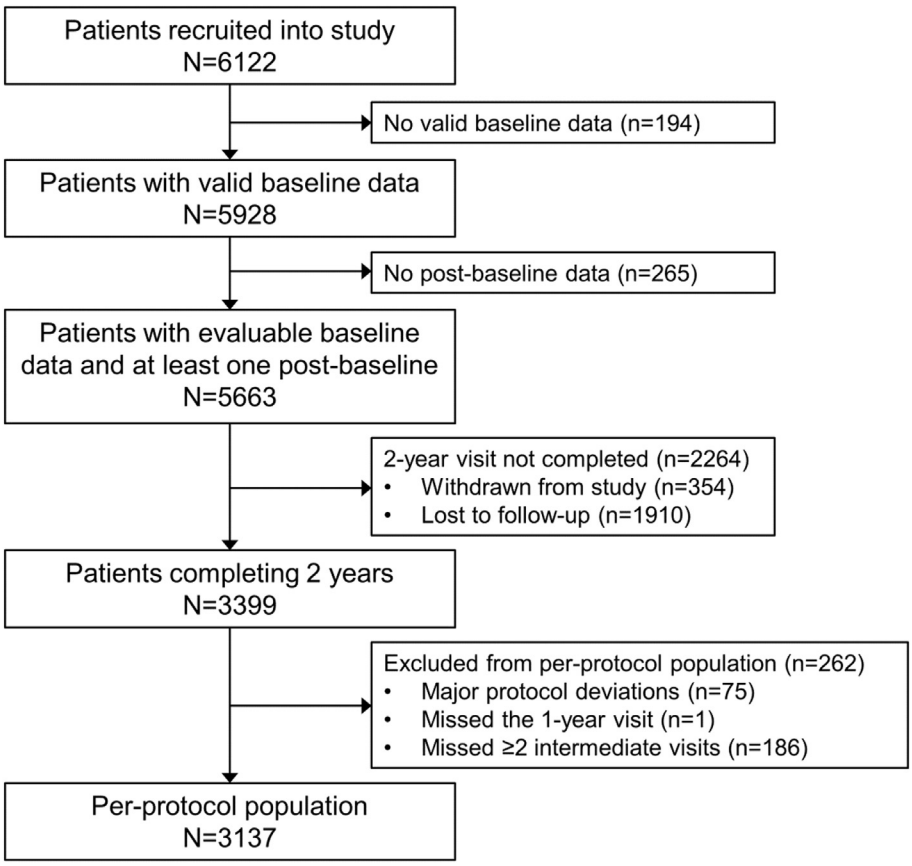

Fig. 1. Patient flow through DACCORD.

symptoms and future risk of exacerbations into account, with the Global Initiative for Chronic Obstructive Lung Disease suggesting a combined assessment [1]. A key driver of the costs [2,3] and healthcare resource utilisation [4,5] of COPD is exacerbations (in addition to comorbidities [6]). Clinical trials for new treatments (especially those conducted to support regulatory approval) are often designed around exacerbation prevention – and perhaps as a consequence exacerbation reduction has become considered the main focus of treatment. However, the main day-to-day impact of the disease on patients is associated with symptoms (or coping strategies to avoid symptoms) – and symptoms are the main driver for patients to visit their physician [7].

The majority of data on the progression of COPD come from randomised, interventional clinical trials, such as TORCH and UPLIFT [8,9]. Such studies tend to recruit relatively narrow, selected populations, and so may not be generalizable. Furthermore, the specialised nature of the investigators may mean that the care that these patients receive may not be representative of standard care. Observational studies conducted in broader populations therefore have an important role in examining COPD disease progression, such as the Copenhagen City Heart Study [10]. Although these studies support the theory that COPD is a progressive disease, this was most marked in specific subgroups of patients, for example those with moderate airflow limitation [11], suggesting that progression is not inevitable.

DACCORD, or Die ambulante Versorgung mit langwirksamen Bronchodilatatoren: COPD-Register in Deutschland (English translation: Outpatient Care With Long-Acting Bronchodilators: COPD Registry in Germany) is a non-interventional study, being conducted in primary and secondary care in Germany, that seeks to measure the impact of COPD (including exacerbations) on patients over a 2-year follow-up period. It is, to our knowledge, the largest such study in COPD to date.

2. Materials and methods

2.1. Trial design

As this is a non-interventional study, specific visits are not mandated by the protocol. However, consistent with usual care in Germany, it was anticipated that data would be recorded approximately every three months. At the baseline visit, data collected in Internet-based electronic case report forms included: demographic and disease characteristics; prescribed COPD medication; COPD Assessment Test (CAT); exacerbations in the 6 months prior to entry (defined based on prescription of oral steroids and/or antibiotics or hospitalization); and forced expiratory volume in 1 s (FEV_1). At 3-monthly visits exacerbations data were collected. At the 1-year and 2-year visits, data collected included prescribed COPD medication, CAT, exacerbations, and lung function. Full details of the methods have been previously published [12], together with the detailed baseline characteristics of the patients recruited [13], and the first year follow-up [14].

2.2. Participants

The main inclusion criteria were a diagnosis of COPD fulfilling the German COPD Disease Management Program (DMP) criteria (one of which is that COPD is confirmed by spirometry testing), age ≥40 years, and initiating or changing COPD maintenance