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Title: Effectiveness of varenicline as an aid to smoking cessation in primary care: An observational study

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Body: Introduction: The effectiveness and safety of varenicline have been well established in randomized controlled trials. In the primary care setting, in which varenicline is commonly prescribed, only limited information is available on its use in patients with smoking-related comorbidities. Objective: To assess the efficacy and safety of varenicline in a large sample of patients seeking smoking cessation treatment through their general practitioners. Methods: This was a 12-week, prospective, observational, non-comparative phase IV trial conducted in Germany. The primary endpoint was the 7-day point prevalence of abstinence rate at Week 11–12, evaluated by verbal report using the nicotine use inventory. Results: Overall 1391 subjects were enrolled; 1177 received study medication and were evaluated for efficacy and safety. A total of 66.7% participants had at least one concurrent comorbidity, chronic obstructive pulmonary disease (35.5%), hypertension (29.6%), depression (10.4%), diabetes mellitus (8.2%), and asthma (7.9%) being the most commonly reported. In the 7-day period between Weeks 11 and 12, 837 of 1177 subjects (71.1%; 95% confidence interval: 68.5, 73.7) were abstinent. A total of 205 all-causality adverse events were reported in 130 subjects (11.0%), of which 189 (in 122 participants [10.4%]) were considered treatment-related, and 2.2% were classified as serious or severe. There were no fatal adverse events. Conclusion: These real-world data indicate that even in a setting outside of the clinical trial environment, and in patients with smoking-related comorbidities, varenicline is an effective smoking cessation aid with an acceptable safety profile.