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Association between *PRO 160/120* prescriptions and incidence of benign prostatic hyperplasia complications in Germany: a retrospective cohort study

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Abstract

The present study aims to analyze the impact of *PRO 160/120* prescriptions on the incidence of urinary incontinence, polyuria (including nocturia), urinary retention, and erectile dysfunction in a real-world setting in Germany and to compare these data with data for the 5-ARIs finasteride and dutasteride, and the α 1-adrenoceptor antagonists tamsulosin and tamsulosin/dutasteride fixed-dose combination. This retrospective study was based on the IQVIA Disease Analyzer database and included male patients with an initial prescription of *PRO 160/120*, finasteride, dutasteride, tamsulosin, or tamsulosin/dutasteride fixed-dose combination between January 2010 and September 2020. Multivariable logistic regression analyses adjusted for age, health insurance, specialty, and relevant co-diagnoses were performed to estimate the association between *PRO 160/120* prescriptions and incidence of pre-defined outcomes. A total of 77,923 patients were included in the study, 3,035 of whom received *PRO 160/120*. *PRO 160/120* was significantly associated with reduced incidence of urinary incontinence (OR: 1.48; 95% CI: 1.10-1.98) and urinary retention compared to tamsulosin (OR: 3.39; 95% CI: 1.75-6.57 and tamsulosin/dutasteride (OR: 2.81; 95% CI: 1.35-5.82). Furthermore, *PRO 160/120* significantly reduced the incidence of erectile dysfunction compared to dutasteride (OR: 2.79; 95% CI: 1.49-5.25). At the same time, patients receiving *PRO 160/120* showed the same incidence of the remaining complications as those taking the reference substances. In conclusion, we observed a significant association between *PRO 160/120* prescription and reduced incidence of urinary incontinence and urinary retention compared to tamsulosin and tamsulosin/dutasteride, as well as reduced incidence of erectile dysfunction compared to dutasteride.

Keywords: PRO 160/120; Prostagutt®; benign prostatic hyperplasia; erectile dysfunction; urinary incontinence.

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