

Suicide-related event rates were low but higher among men with prior psychiatric disorders or sexual dysfunction, with younger men in the general population and older BPH patients showing relatively higher incidence. Slightly higher rates were observed in BPH patients treated with alpha blockers, though comparisons were limited due to lack of adjustment and underreporting.

DARWIN EU® - Incidence of suicide-related events among adult male patients treated for androgenetic alopecia and benign prostatic hyperplasia in Europe

Background: Finasteride and dutasteride are prescribed in Europe to treat androgenetic alopecia and benign prostatic hyperplasia (BPH). Post marketing observational studies have reported signals of mood changes, depression, and, rarely suicidal ideation in patients using finasteride.

Objectives: This study aimed to evaluate the incidence rates of suicide-related events in adult male patients newly diagnosed with androgenetic alopecia or BPH who were exposed to medications use to treat these conditions.

Results

IRs by Population

IRs of suicide-related events in the general adult male population varied substantially across data sources. The highest IR was observed in CPRD-Gold at 1.47/1,000 PYs (95% CI: 1.46–1.49), followed by NAJS at 0.53 (95% CI: 0.52, 0.55), IPCI at 0.49 (95% CI: 0.47–0.51), BIFAP at 0.42 (95% CI: 0.42–0.43), and SIDIAP at 0.34 (95% CI: 0.33–0.34). In the androgenetic alopecia cohort, estimates were available only for a few data sources and ranged from 0.42/1,000 PYs in BIFAP to 2.08 in CPRD-GOLD, with several data sources reporting a small counts. Among men with BPH, IRs ranged from 0.12/1,000 PYs in InGef RDB to 0.88 in CPRD-GOLD. (Figure 1)

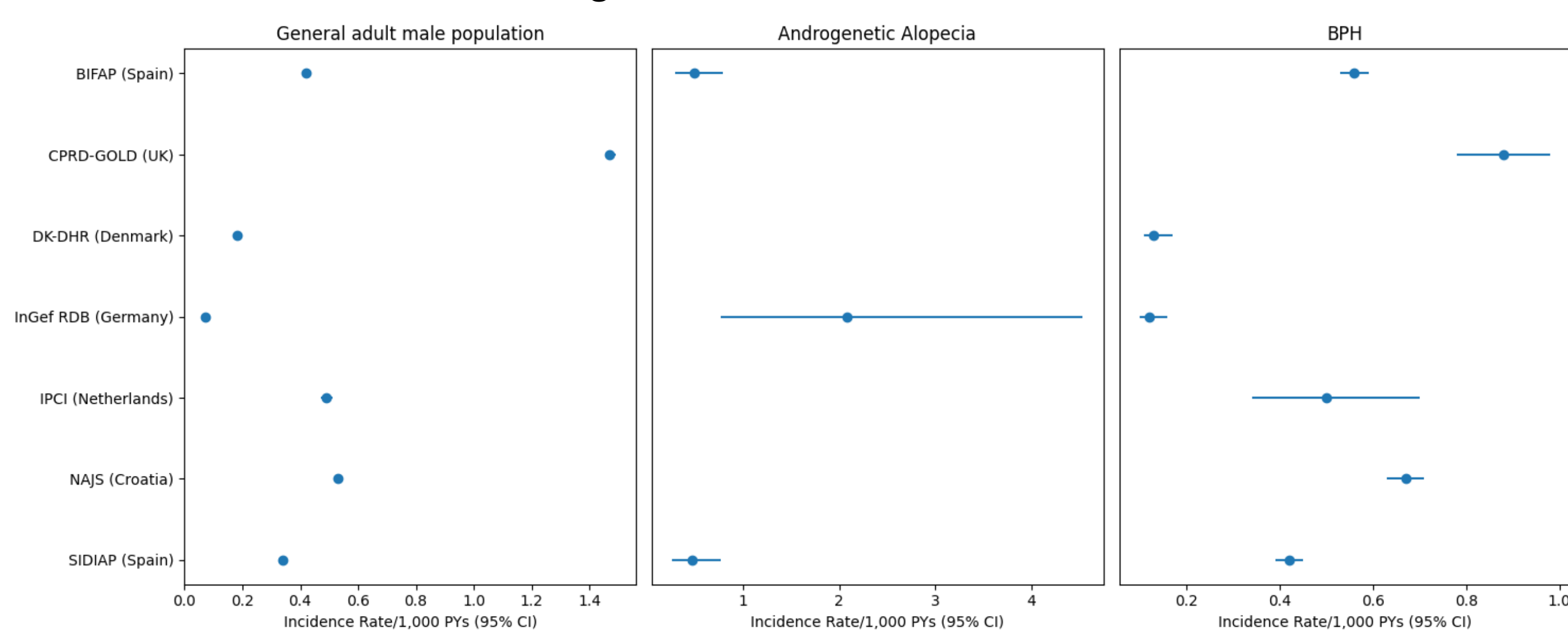
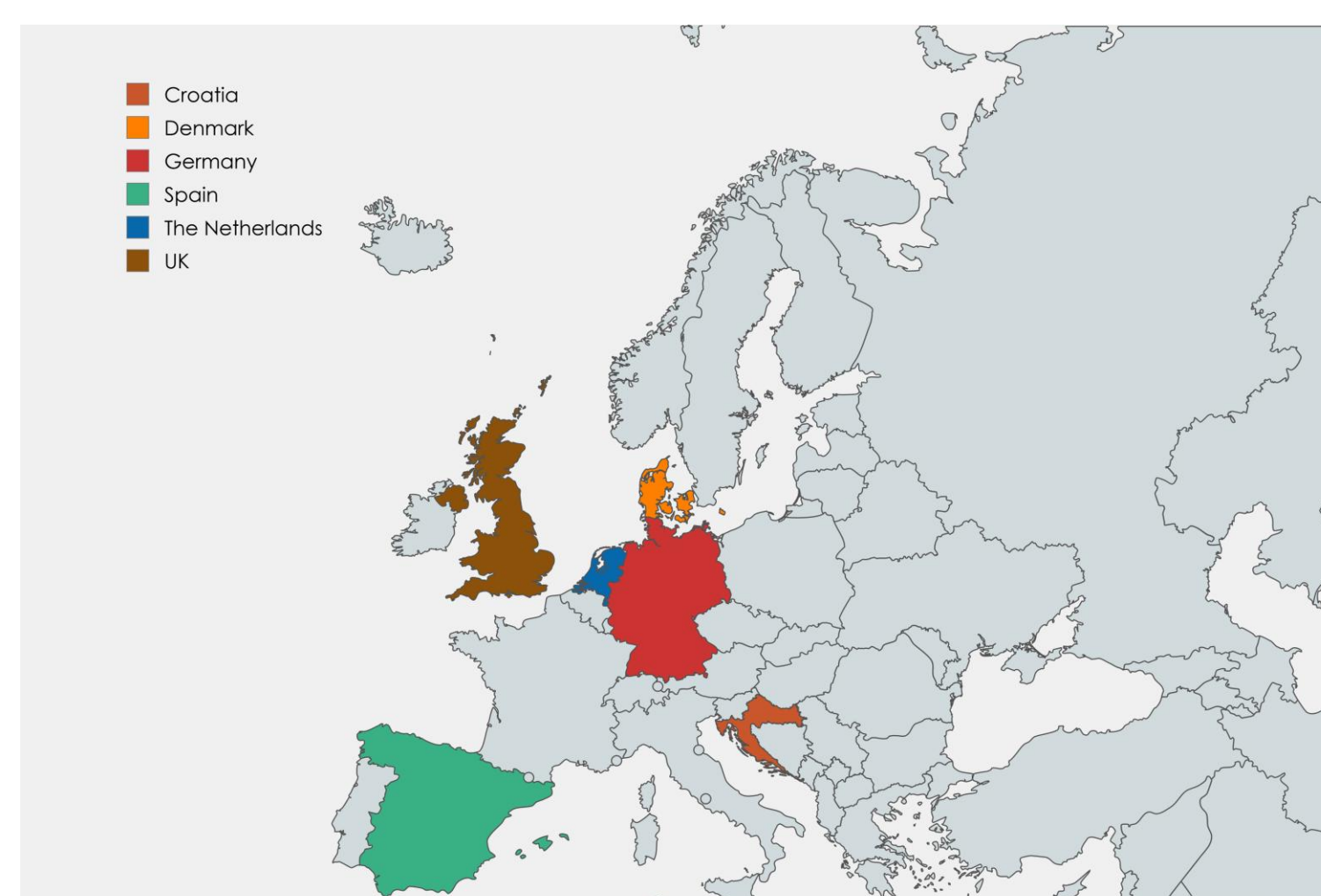


Figure 1. Incidence rates of composite suicide-related events outcome per 1,000 PYs in the general adult male, androgenetic alopecia, and BPH during the study period.

Methods

1 In this population-level cohort study, we included all adult male patients (≥ 18 years) recorded in participating data sources during the study period. Two sub-cohorts were defined: men newly diagnosed with androgenetic alopecia and men newly diagnosed with BPH, within which nested cohorts were created for individuals initiating treatments of interest and those not initiating treatment at diagnosis.

Data were obtained from seven routinely collected healthcare data sources in the DARWIN EU® network across six European countries (BIFAP and SIDIAP in Spain, CPRD-Gold in the UK, DK-DHR in Denmark, InGef RDB in Germany, IPCI in the Netherlands, and NAJS in Croatia), all mapped to the OMOP common data model.



3 Analytical methods

Incidence rates (IRs) of suicide-related events per 1,000 person-years (PYs) were estimated in the general adult male population and in adult male patients diagnosed with androgenetic alopecia and BPH. Within these indications, IRs were also calculated among patients exposed to the drugs of interest (i.e., treatments of androgenetic alopecia and BPH). Overall IRs (and 95% Poisson confidence intervals) were reported as well as stratified by age categories, history of psychiatric disorders, and history of sexual dysfunction.

The study period was from 1 January 2010 to the end of 2024 or the latest available data.

2 Variables

Exposures

Conditions of interest (androgenetic alopecia and BPH) and treatments for these conditions (i.e., finasteride, dutasteride, topical minoxidil, alpha blockers, tadalafil, and tadalafil + finasteride/dutasteride).

Outcome

A composite suicide-related events outcome including the first recorded occurrence of any of the following events: completed suicide, attempted suicide, suicide ideation, and intentional self-harm.

Relevant covariates

Age groups, history of psychiatric disorder, and history of sexual dysfunction.

Limitations: This study has limitations inherent to the use of routinely collected healthcare data. Suicide-related events may be underreported or misclassified, particularly within primary care data and across different coding systems and data sources. Other limitations include incomplete ascertainment of conditions such as androgenetic alopecia and medication exposure, including over-the-counter and off-label use, as well as potential inaccuracies in diagnosis dates in some claims databases. In addition, residual confounding may persist because of unmeasured differences between the populations under comparison.



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