Web appendix: Sensitivity analyses

Sensitivity Analysis 1: Risk for hypotension with tamsulosin using the self-controlled case series approach and restricting the analysis only to the first hypotension event.

	Total N	Events N	Person-Years	Rate/100 Person-Years	Rate Ratio (95%CI)
Model 1: Cohort Analysis					
New Use (weeks 1-4)	2248	179	167	107.2	2.76 (2.31 to 3.30)
New Use (weeks 5-8)	2076	74	118	62.7	1.76 (1.37 to 2.27)
New Use (weeks 9-12)	1404	63	116	54.3	1.62 (1.23 to 2.13)
Restarting therapy (weeks 1-4)	1104	74	181	40.9	1.67 (1.30 to 2.14)
Restarting therapy (weeks 5-8)	1070	69	172	40.1	1.72 (1.33 to 2.23)
Restarting therapy (weeks 9-12)	912	39	133	29.3	1.27 (0.91 to 1.78)
Maintenance Therapy	1357	520	1923	27.0	1.42 (1.23 to 1.65)

This sensitivity analysis was conducted to examine the difference in point estimates after restricting the analysis to allowing only one hypotension event. It was done to examine for a potential violation of the exposure dependent event assumption in the self-controlled case series. The similar point estimates with this sensitivity analysis indicate bias from a violation of this assumption is unlikely.

Sensitivity Analysis 2: Risk for hypotension with tamsulosin using the self-controlled case series approach and adjusting for age in 5-year bands (n-1 parameters) and calendar time in 1-year bands (n-1 parameters).

	Total N	Events N	Person-Years	Rate/10,000 Person-Years	Rate Ratio (95%CI)
Model 1: Cohort Analysis					
New Use (weeks 1-4)	2248	185	167	110.8	2.49 (2.10 to 2.97)
New Use (weeks 5-8)	2076	79	118	66.9	1.62 (1.27 to 2.06)
New Use (weeks 9-12)	1404	68	116	58.6	1.50 (1.15 to 1.95)
Restarting therapy (weeks 1-4)	1104	80	181	44.2	1.57 (1.25 to 2.00)
Restarting therapy (weeks 5-8)	1070	74	172	43.0	1.58 (1.23 to 2.03
Restarting therapy (weeks 9-12)	912	42	133	31.6	1.18 (0.85 to 1.62)
Maintenance Therapy	1357	651	1923	33.9	1.35 (1.19 to 1.55)

In this sensitivity analysis, exposures are defined daily to reduce potential misclassification of drug exposure which could produce a bias toward the null. Second, age and calendar year are defined in larger brackets to allow risk to vary by age range and calendar year.