

CHECKPOINT INHIBITOR MONOTHERAPY IS ASSOCIATED WITH LESS CARDIAC TOXICITY THAN COMBINATION THERAPY

MP 14-18

EUGENE B. CONE MD,^{1,2,3} LORINE HAEUSER MD,^{1,2} STEPHEN REESE MD,¹ MAYA MARCHESE MS,^{1,2} JUNAID NABI MD, MPH,^{1,2} KERRY KILBRIDGE MD MSc,^{1,4} QUOC-DIEN TRINH MD^{1,2}

1 - Division of Urological Surgery, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA

2 - Center for Surgery and Public Health, Department of Surgery, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA

3 - Department of Urology, Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA

4 - Lank Center for Genitourinary Oncology, Dana Farber Cancer Center, Harvard Medical School, Boston, MA, USA

METHODS: PHARMACOVIGILANCE WITH VIGIBASE

- Traditional Approach
 - Test of independence (chi square) between the drug and adverse event

- Pharmacovigilance Approach
 - Compare the likelihood of an AE with the drug of interest to the likelihood of that AE with any other drug
 - Compensates for absence of reported cohort taking drug with no adverse events

| | + Drug A | - Drug A | |
|------------------|----------|----------|--|
| Adverse Event | A | B | |
| No Adverse Event | C | D | |
| | | | |

| | + Drug A | - Drug A | |
|----------------------------|----------|----------|--|
| Drug A-Related AE | A | B | |
| All Other-Drug-Related AEs | C | D | |
| | | | |

| | Count | Expected Count | Empirical Bayes Estimator | Reporting Odds Ratio (95% CI) |
|------------------------------|-------|----------------|---------------------------|-------------------------------|
| Any cardiac event | | | | |
| Monotherapy | 2278 | 3350 | 0.7 | NA |
| Combination Therapy | 353 | 410 | 0.8 | NA |
| Heart Failure | | | | |
| Monotherapy | 313 | 333.2 | 0.9 | NA |
| Combination Therapy | 25 | 40.8 | 0.4 | NA |
| Myocardial Infarction | | | | |
| Monotherapy | 415 | 753.6 | 0.5 | NA |
| Combination Therapy | 48 | 92.3 | 0.4 | NA |
| Carditis | | | | |
| Monotherapy | 630 | 128.6 | 4.6 | 5.0 (4.6-5.4) |
| Combination Therapy | 107 | 15.8 | 5.7 | 6.9 (5.7-8.3) |
| Arrhythmia | | | | |
| Monotherapy | 701 | 1105.0 | 0.6 | NA |
| Combination Therapy | 150 | 135.4 | 1.0 | NA |
| Valvular Dysfunction | | | | |
| Monotherapy | 9 | 109.9 | 0.05 | NA |
| Combination Therapy | 2 | 13.5 | 0.05 | NA |
| Other | | | | |
| Monotherapy | 210 | 912 | 0.20 | NA |
| Combination Therapy | 21 | 111.7 | 0.13 | NA |