

Lapses in Asthma Control in Patients Who Continued vs. Discontinued Omalizumab

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INTRODUCTION

Little is known about the benefits of continuous omalizumab treatment to asthma patients in real-world settings (Eisner, et.al., *J Asthma* 2012; 49(6); pp.642-8).

OBJECTIVE

This analysis aimed to examine the lapses in asthma control in patients who continued vs. discontinued omalizumab treatment in a real-world setting.

METHODS

- Retrospective cohort study using a large HIPAA-compliant commercial healthcare claims database from 1/1/2008 to 12/31/2010.
- Inclusion criteria:** patients ≥12 years old with ≥2 medical claims associated with asthma (ICD-9-CM: 493.x), ≥2 asthma controller medications in the identification period (1/1/09-12/31/09). In addition, patients had to have ≥6 months of continuous omalizumab use.
- Exclusion criteria:** patients who were not continuously enrolled, OR had a hospitalization for any reason 2 months before the index date, OR had a short burst of oral steroids (≤15 days of supply) 2 months before the index date, OR had a diagnosis of cystic fibrosis (ICD-9-CM: 277.0x) in the pre-index period, OR (for continuous users) who did not continue the medication for ≥3 months after the index date.
- After ≥6 months of omalizumab therapy, patients were stratified as continuers (continued omalizumab until dropout or 12/31/10) or discontinuers (stopped OMA for >90 days) and followed for ≥3 months after the index date.
- For continuers, the index date comprised a random date ≥6 months after omalizumab initiation; for discontinuers, the index date was the date of the last fill of omalizumab.
- Primary outcome:** risk of lapse in asthma control, measured as any asthma-related hospitalization or emergency room (ER) visit, ≥2 oral corticosteroids (OCS) filled in, or ≥6 short-acting beta-agonists (SABA) filled in 1 year, post-index date, reported as episodes per 100 patient-years (PY).

RESULTS

- 414 omalizumab continuers and 240 discontinuers (**Table 1**); median follow-up 415 days.
- Mean age was 46.2 years; 62.5% women; 15.6% had COPD.
- At baseline, the groups were not significantly different in terms of age, sex, asthma physician specialty, chronic conditions and Charlson comorbidity index, use of asthma medications, and asthma medication ratio.
- Discontinuers had no omalizumab use after the discontinuation date.
- Overall, there were 32.5 episodes of lapses in asthma control per 100 PY of follow-up for both groups of patients combined.

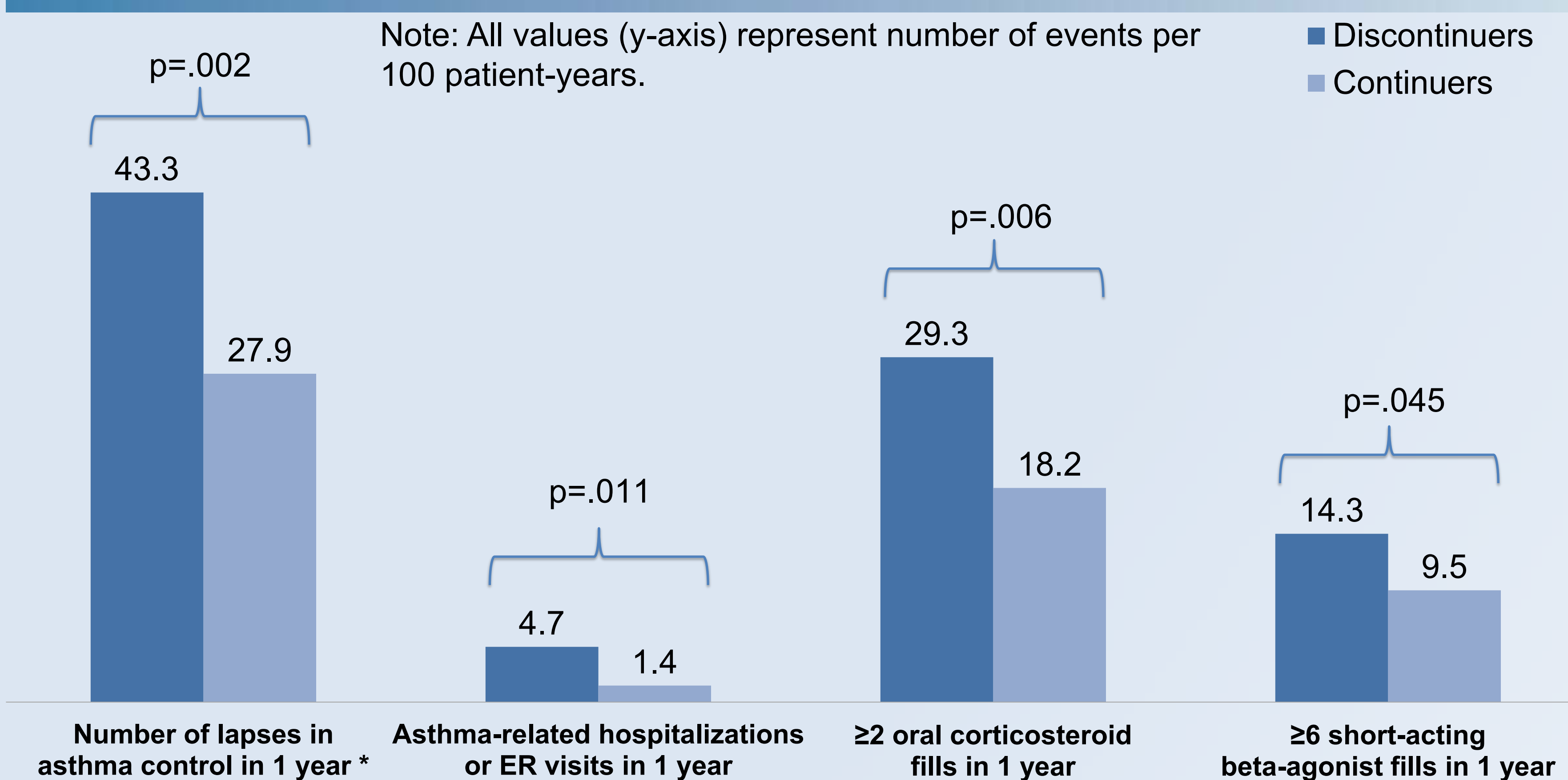
RESULTS (continued)

- Discontinuers had more lapses in asthma control per year (**Figure 1**), and they had a greater risk of lapses in asthma control after adjusting for age, sex, region, and other patient characteristics (**Figure 2**) than continuers.
- Time to first lapse in asthma control was significantly shorter in discontinuers compared to continuers. Median time to reach a lapse in asthma control was 659 days for discontinuers and was not reached by continuers. (**Figure 3**)

TABLE 1. Patient Characteristics

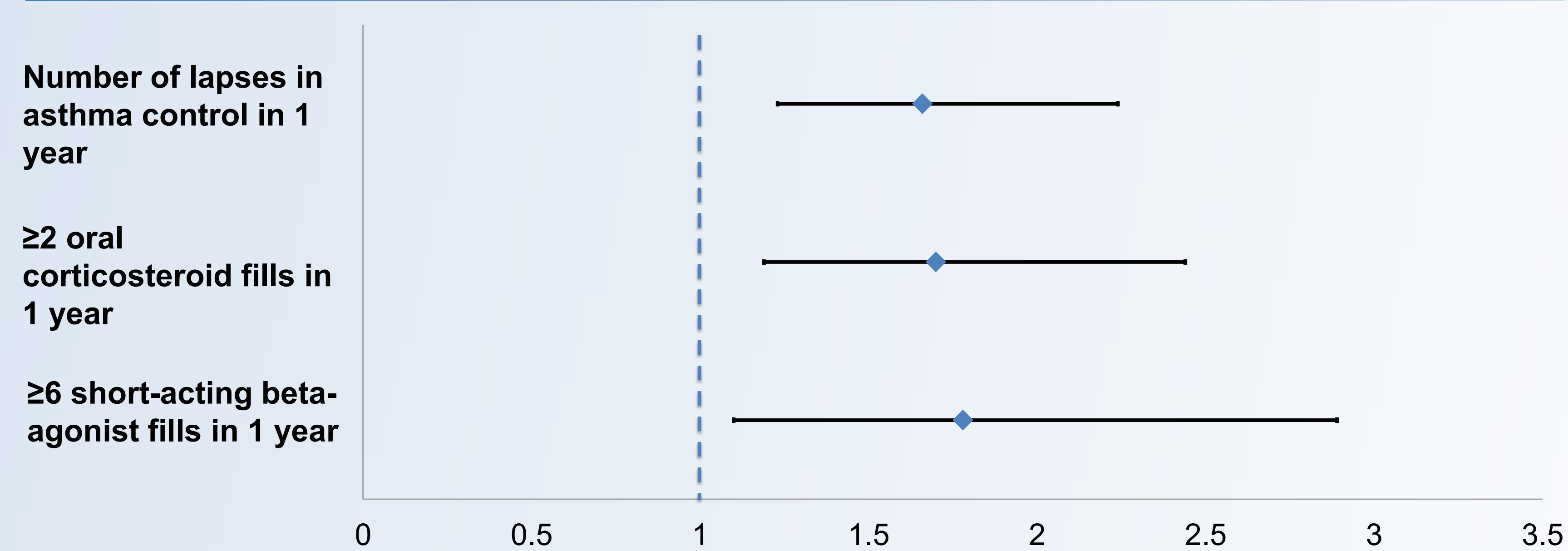
	Discontinuous Users	Continuous Users	All Users	P value
N (%)	240 (36.7)	414 (63.3)	654	
Age in years, mean (SD)	45.3 (14.5)	46.8 (14.0)	46.2 (14.2)	0.185
Female, no. (%)	149 (62.1)	260 (62.8)	409 (62.5)	0.855
No. of chronic conditions, mean (SD)	3.9 (1.9)	3.8 (2.1)	3.9 (2.0)	0.633
Charlson comorbidity index, mean (SD)	1.5 (1.0)	1.5 (1.2)	1.5 (1.1)	0.624

FIGURE 1. Lapses in Asthma Control in Patients who Discontinued vs. Continued Omalizumab after ≥6 Months of Treatment



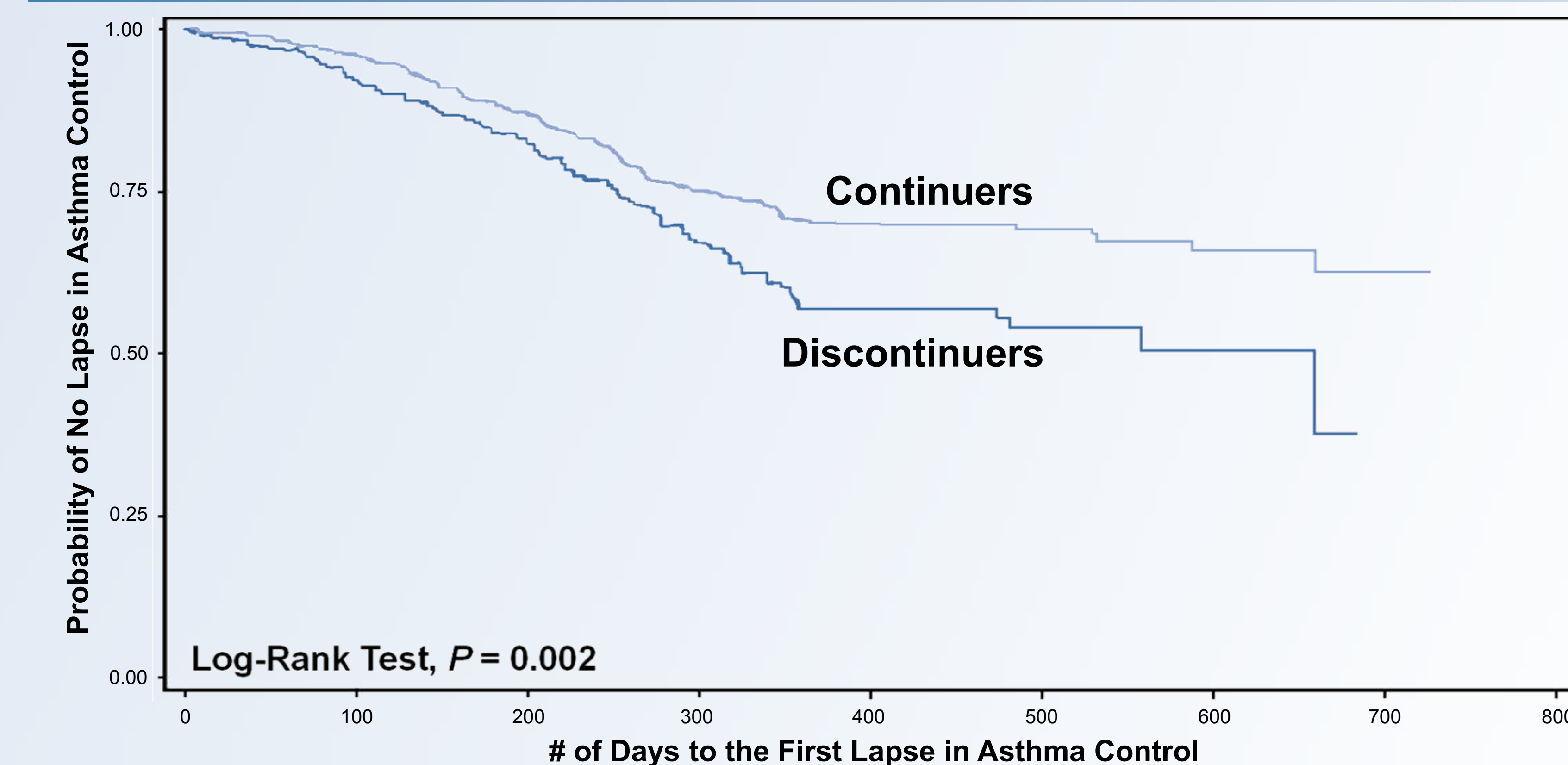
* Patients could have any or all of the potential events defined as lapse in asthma control.

FIGURE 2. Adjusted Hazard Ratio of Lapses in Asthma Control in Patients who Discontinued vs. Continued Omalizumab



Note: Bars represent 95% confidence intervals.

FIGURE 3. Time to Lapse in Asthma Control



CONCLUSION

Real-world evidence suggests that asthma patients who receive continuous (≥6 months) omalizumab treatment experience fewer lapses in asthma control than those who discontinue omalizumab after 6 months.