

Impact of Rifaximin Use on Overt Hepatic Encephalopathy (OHE) Rehospitalizations Post Discharge from an OHE Hospitalization in Commercially, Medicare, and Medicaid Insured Patients

Arun B. Jesudian¹; Patrick Gagnon-Sanschagrin²; Rebecca Bungay²; Kaitlyn Easson²; Aditi Shah²; Annie Guérin²; Aaron Samson³; Olamide Olujuhunge³; Brock Bumpass³

¹Weill Cornell Medicine, New York, NY, USA, 10065; ²Analysis Group, Inc., Montréal, QC, Canada, H3B 0G7; ³Bausch Health, Bridgewater, NJ, USA, 08807

Background

- Overt hepatic encephalopathy (OHE) is a severe neurologic complication of cirrhosis, which manifests with various symptoms related to reduced brain function, altered consciousness, and confusion¹; and is characterized by recurring episodes that require rehospitalization²
- Better understanding the impact of post-discharge rifaximin use on OHE rehospitalizations in patients with OHE in real-world practice may inform management and improve patient outcomes

Objectives

To describe and compare rates of OHE rehospitalization following an initial OHE hospitalization among commercial, Medicare, and Medicaid patients treated with rifaximin (± lactulose) versus those who are not

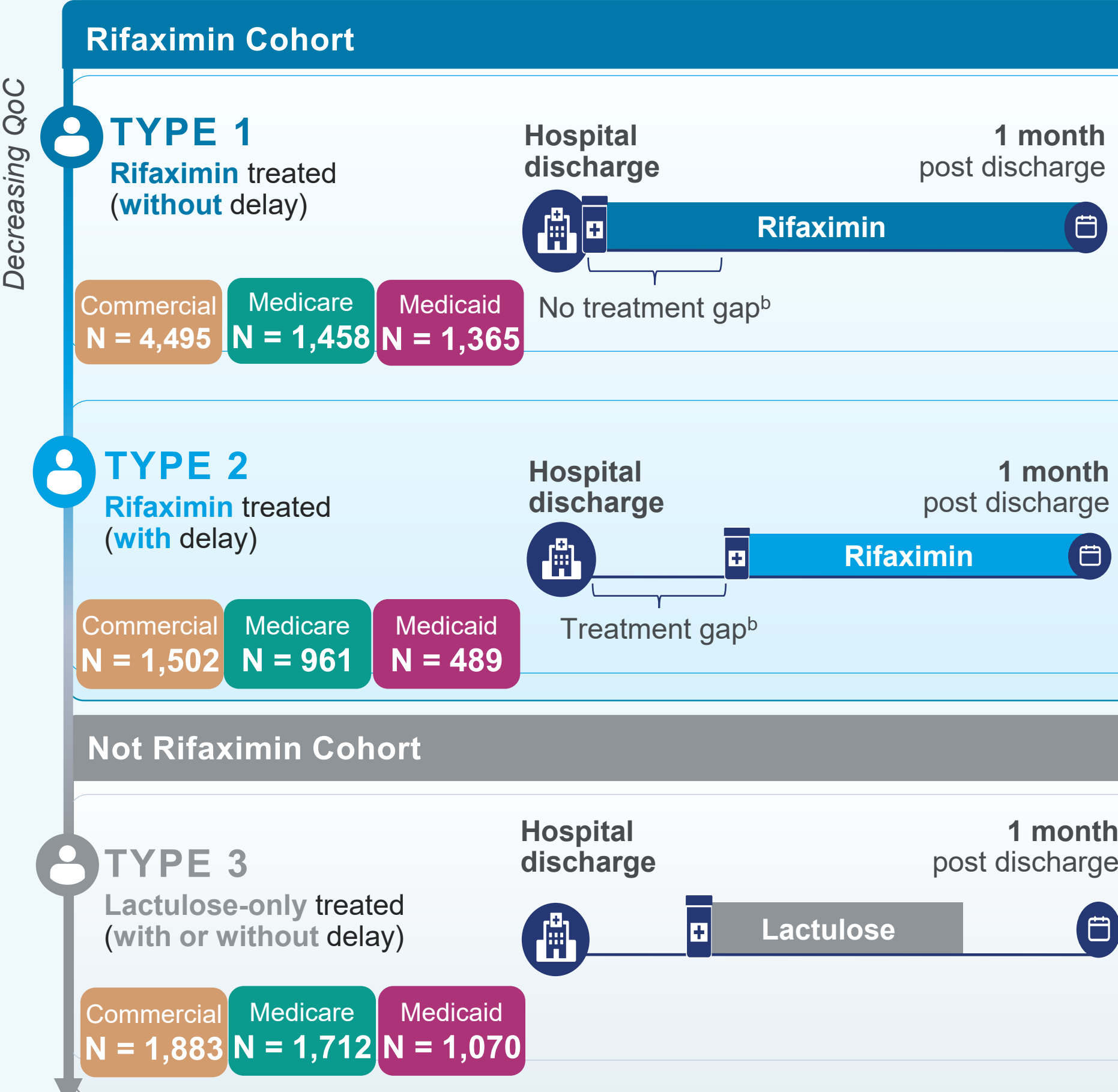
Methods

Data source: Komodo Research Dataset (KRD+) from 01/2016 - 09/2023

Retrospective cohort study

- Study population:** Adults with an OHE hospitalization^a (index hospitalization), stratified by insurance type at index date (day after discharge from the index hospitalization)
- Cohort classification:** Patients in each insurance sample were classified into two mutually exclusive cohorts based on treatment received within 30 days of index hospitalization
 - Cohorts were further stratified into three subgroups representing decreasing quality of care (QoC) based on medical expert input

Figure 1. Study design and cohorts



Measures, outcomes, and statistical analyses

- Among each cohort, baseline (i.e., 6-month period prior to the index hospitalization) characteristics, characteristics of the index hospitalization, proportion of 30-day OHE rehospitalizations, and number of subsequent OHE hospitalizations were reported
- The impact of rifaximin use on the risk of 30-day OHE rehospitalization and annual rates of subsequent OHE hospitalizations were described and compared by cohort and by QoC subgroups, separately:
 - 30-day OHE rehospitalization rates: Logistic regressions adjusted for characteristics, reported as odds ratios (ORs) and point estimates
 - Annual rates of OHE rehospitalizations: Negative binomial regressions adjusted for characteristics, reported as incidence rate ratios (IRRs) and point estimates

^aOHE hospitalization was defined as either (1) a primary diagnosis for OHE (ICD-10-CM: K72.90, K72.91, K70.41, K71.11, K72.01, K72.11, K76.82) AND a diagnosis-related group (DRG) code of 441, 442, 443, or (2) a prescription of rifaximin 550mg twice daily with >30 days supply during the hospital stay
^bTreatment gap was defined as a period of ≥ 1 day following discharge from the index OHE hospitalization without a prescription fill for rifaximin (Rifaximin Cohort) or lactulose (Not Rifaximin Cohort)

Results

COMMERCIAL	Table 1. Demographics and clinical characteristics		MEDICARE			MEDICAID		
	Rifaximin Cohort N=5,997	Not Rifaximin Cohort N=1,883		Rifaximin Cohort N=2,419	Not Rifaximin Cohort N=1,712		Rifaximin Cohort N=1,854	Not Rifaximin Cohort N=1,070
Demographic characteristics			Demographic characteristics			Demographic characteristics		
Age (years), mean ± SD [median]	54.7 ± 8.7 [57.0]	55.8 ± 8.3 [58.0]	Age (years), mean ± SD [median]	67.5 ± 9.5 [68.0]	69.3 ± 8.7 [70.0]	Age (years), mean ± SD [median]	51.1 ± 9.8 [53.0]	52.7 ± 9.3 [55.0]
Female, N (%)	2,348 (39.2%)	796 (42.3%)	Female, N (%)	1,181 (48.8%)	835 (48.8%)	Female, N (%)	831 (44.8%)	496 (46.4%)
Medicare Advantage, N (%)			Medicare Advantage, N (%)	2,187 (90.4%)	1,607 (93.9%)			
Clinical characteristics			Clinical characteristics			Clinical characteristics		
CirCom score, N (%)			CirCom score, N (%)			CirCom score, N (%)		
0	2,936 (49.0%)	894 (47.5%)	0	607 (25.1%)	486 (28.4%)	0	507 (27.3%)	309 (28.9%)
1 - 3	1,916 (31.9%)	626 (33.2%)	1 - 3	813 (33.6%)	542 (31.7%)	1 - 3	935 (50.4%)	556 (52.0%)
≥ 4	1,145 (19.1%)	363 (19.3%)	≥ 4	999 (41.3%)	684 (40.0%)	≥ 4	412 (22.2%)	205 (19.2%)
Patients with a MELD-Na score, N (%)	406 (6.8%)	107 (5.7%)	Patients with a MELD-Na score, N (%)	248 (10.3%)	128 (7.5%)	Patients with a MELD-Na score, N (%)	194 (10.5%)	64 (6.0%)
MELD-Na score, mean ± SD [median]	20.0 ± 7.5 [20.0]	19.0 ± 6.8 [20.0]	MELD-Na score, mean ± SD [median]	16.9 ± 6.9 [17.0]	15.8 ± 6.6 [15.0]	MELD-Na score, mean ± SD [median]	19.0 ± 7.6 [18.0]	17.7 ± 6.4 [18.0]
Frailty index (%), mean ± SD [median]	17.7 ± 6.0 [16.8]	17.9 ± 6.2 [16.9]	Frailty index (%), mean ± SD [median]	23.0 ± 8.1 [21.7]	22.4 ± 7.8 [21.4]	Frailty index (%), mean ± SD [median]	21.4 ± 7.4 [21.0]	20.7 ± 7.0 [20.1]
Length of index OHE hospitalization (days), mean ± SD [median]	11.0 ± 13.3 [6.0]	7.2 ± 9.4 [4.0]	Length of index OHE hospitalization (days), mean ± SD [median]	9.7 ± 14.8 [6.0]	6.2 ± 7.6 [4.0]	Length of index OHE hospitalization (days), mean ± SD [median]	11.5 ± 13.5 [7.0]	7.3 ± 7.7 [5.0]
Duration of follow-up period (months), mean ± SD [median]	4.9 ± 6.6 [2.5]	2.6 ± 3.4 [1.6]	Duration of follow-up period (months), mean ± SD [median]	5.5 ± 7.5 [2.6]	3.3 ± 4.2 [2.0]	Duration of follow-up period (months), mean ± SD [median]	4.9 ± 6.9 [2.2]	3.0 ± 3.3 [1.9]

Figure 2. 30-day risk of OHE rehospitalization

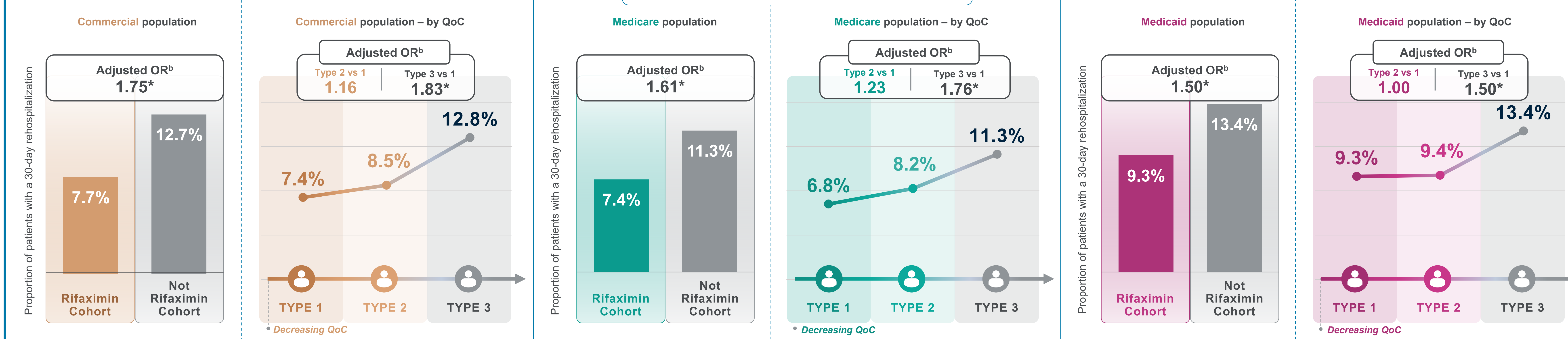
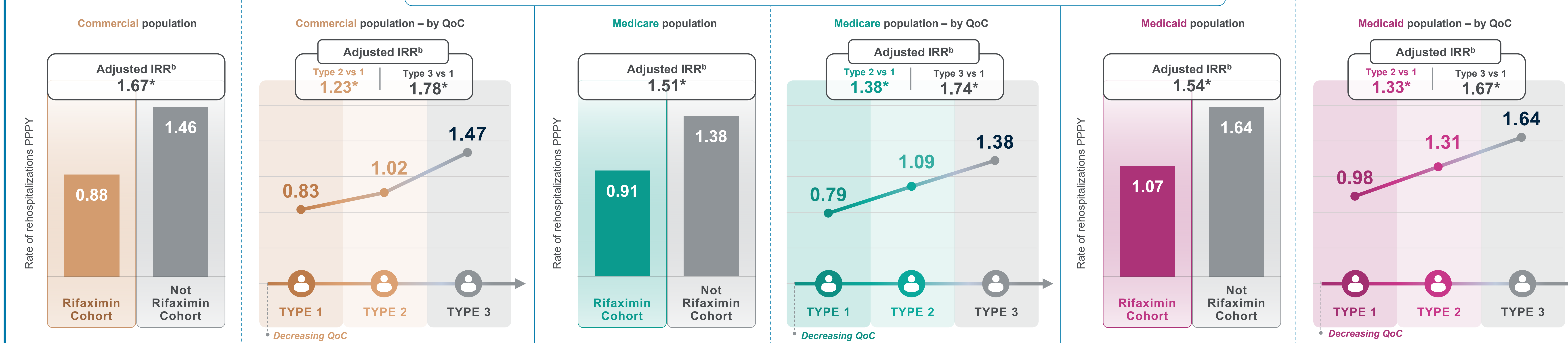


Figure 3. Annual rates of subsequent OHE hospitalizations per patient per year (PPPY)



Note: ^bModels were adjusted for age, sex, region, race/ethnicity, baseline comorbidities, and index characteristics. *Significant at the 5% level.

Conclusions

Among commercial, Medicare, and Medicaid insured patients with an OHE hospitalization:

- Patients treated with rifaximin post-discharge had a lower risk of 30-day OHE rehospitalization than patients not treated with rifaximin
- Patients treated with rifaximin post-discharge had a lower annual rate of subsequent OHE rehospitalizations than patients not treated with rifaximin
- Decreasing quality of care resulted in increased risk of 30-day rehospitalizations and annual rates of OHE rehospitalizations post-discharge

Limitations

- This claims-based study is subject to common limitations including billing inaccuracies and missing data
- Patients with OHE were identified using an algorithm developed in collaboration with medical experts based on real-world clinical practice for coding for OHE
- Results limited to commercial, Medicare, and Medicaid insured populations and may not be representative of all US adults

References

- Ferenci P. *Gastroenterol Rep.* 2017;5(2):138-147.
- Vilstrup H, et al. *Hepatology.* 2014;60(2):715-735.

Sponsorship

Design, study conduct, and financial support for the study were provided by Bausch Health Companies, Inc.; Bausch Health Companies, Inc. participated in the interpretation of data and production of the abstract; all authors contributed to the development of the publication and maintained control over the final content.

Disclosures

ABJ has received consulting fees from Bausch Health, Salix Pharmaceuticals, Novo Nordisk, and Orphan SA; and is a member of the Speakers Bureau for Bausch Health, Salix Pharmaceuticals, and Madrigal Pharmaceuticals. PGS, RB, KE, AS, and AG are employees of Analysis Group, Inc., a consulting company that has provided paid consulting services to Bausch Health, which funded the development and conduct of this study. AS, OO, and BB are employees of Bausch Health, and OO and BB have stock ownership in Bausch Health.