Prevalence of Hypertension Over (Calendar) Time Among People With Narcolepsy Treated With Oxybate

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Introduction

- Narcolepsy is associated with cardiovascular, cardiometabolic, and renal comorbidities; higher sodium intake is associated with greater risk of these conditions, especially hypertension (HTN)¹⁻⁵
- The American Heart Association recommends sodium intake of no more than 2300 mg per day, and ideally less than 1500 mg per day, for adults⁶
- Sodium oxybate (SXB), approved to treat cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy, contains 1100 to 1600 mg of sodium per daily standard dosage, or 47.8% to 69.6% of the maximum daily intake of 2300 mg recommended by the National Academies of Sciences, Engineering and Medicine for chronic disease risk reduction⁸
- Low-sodium oxybate (LXB), containing 92% less sodium than the previously approved SXB, became available to the US market in November 2020^{7,9}

Objective

 We evaluated the prevalence of HTN over calendar time among individuals with narcolepsy and assessed whether availability of LXB impacted HTN prevalence among new SXB initiators (initiators of branded or authorized generic twice-nightly SXB or once-nightly SXB)

Methods

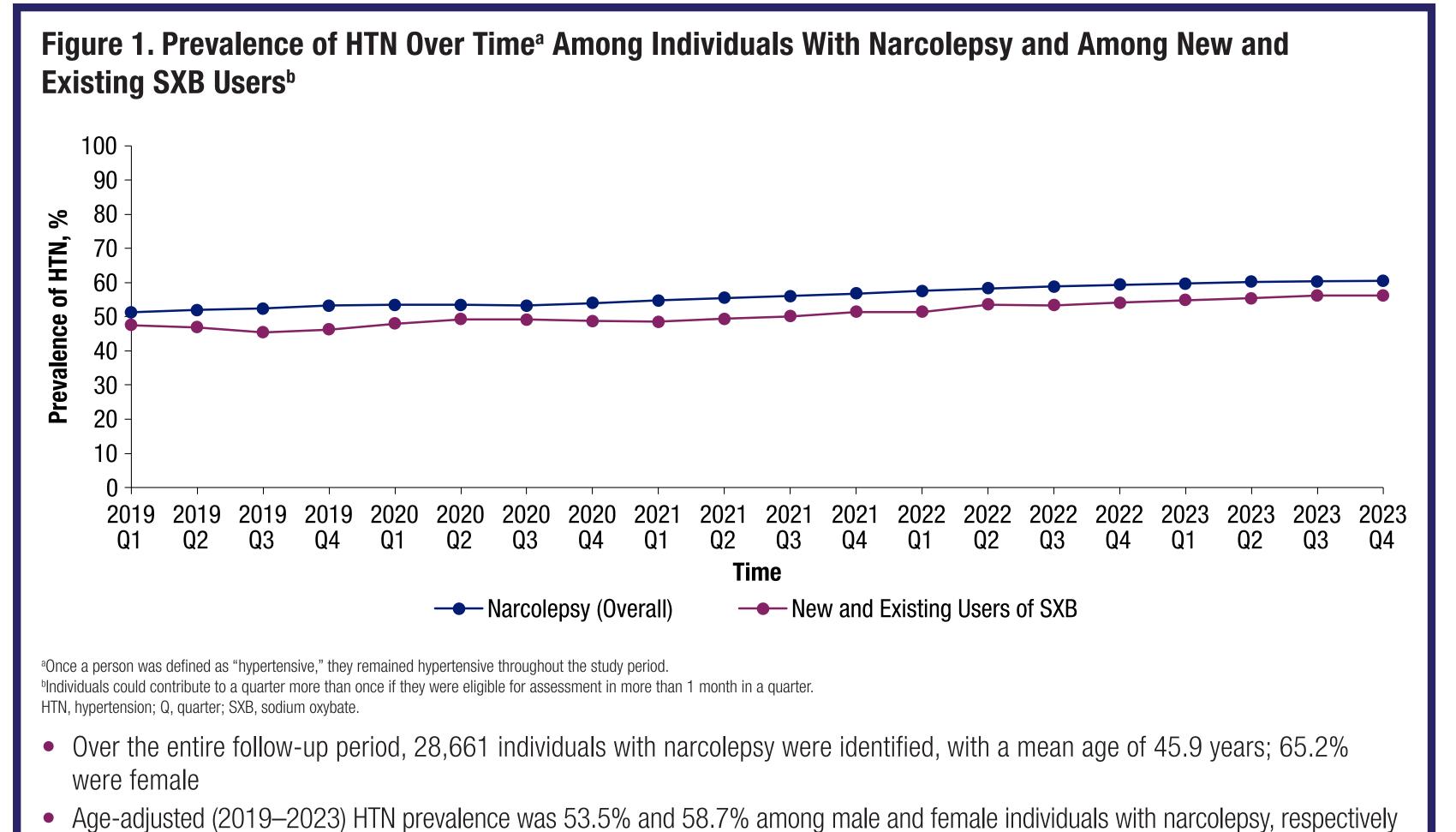
- A cross-sectional observational study using the Optum[®] Market Clarity dataset (2019–2023) examined individuals with narcolepsy, aged 18 to 84 years, with ≥6 months of insurance enrollment prior to and including cohort entry month/year
- Narcolepsy was defined by any 2 medical claims ≥1 day apart with a diagnosis for narcolepsy in any position, using International Classification of Diseases, 10th Revision (ICD-10) codes G47.411, G47.419, G47.421, or G47.429
- HTN was defined by ≥2 outpatient claims ≥1 day apart with a diagnosis in any position, using ICD-10 codes, or by ≥1 prescription claim for an antihypertensive medication
- Monthly HTN prevalence, age-standardized to the 2020 US Census, was calculated among (1) individuals with narcolepsy overall (treatment agnostic), (2) new and existing SXB users, (3) new SXB initiators, (4) new LXB initiators, and (5) SXB-to-LXB switchers
- Monthly HTN prevalence among individuals with narcolepsy was also stratified by age and sex
- Monthly estimates were averaged over quarters due to small sample sizes in each month
- An interrupted time series analysis assessed change (95% confidence interval [CI]) in age-adjusted HTN prevalence before and after LXB availability in the US market (November 2020) in new initiators of any SXB
- Scan the QR code in the lower right corner of the poster to access the model parameters

References: 1. Black J, et al. *Sleep Med.* 2017;33:13-18. **2.** Lipford MC, et al. *Sleep Adv.* 2024;5(1):zpae067. **3.** Ben-Joseph RH, et al. *Sleep.* 2023;46(10):zsad161. **4.** Ohayon MM. *Sleep Med.* 2013;14(6):488-492. **5.** Strazzullo P, Abate V. *Adv Nutr.* 2025:100409. **6.** American Heart Association. How much sodium should I eat per day? 2024. https://www.heart.org/en/healthy-living/healthy-eating/eat-smart/sodium/how-much-sodium-should-i-eat-per-day. Accessed March 13, 2025. **7.** Junnarkar G, et al. *Expert Opin Drug Discov.* 2022;17(2):109-119. **8.** National Academies of Sciences, Engineering, and Medicine. *Dietary Reference Intakes for Sodium and Potassium.* Washington, DC: National Academies Press; 2019. **9.** Heo YA. *CNS Drugs.* 2022;36(5):541-549. **10.** Jennum PJ, et al. *Sleep Med Rev.* 2021;58:101440. **11.** Kwon Y, et al. *J Am Heart Assoc.* 2024;13(16):e035168.

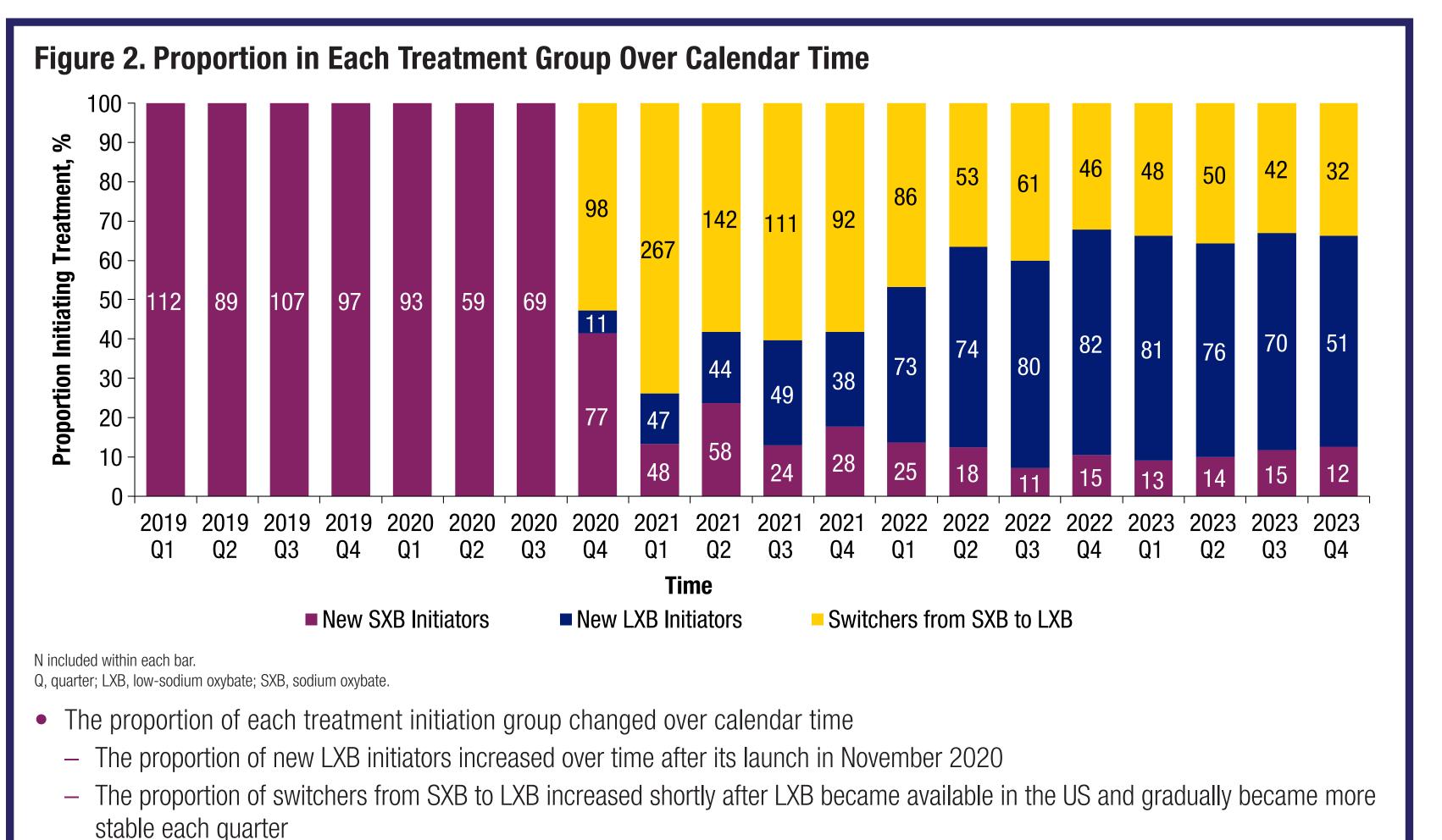
Support and Acknowledgments: This study was supported by Jazz Pharmaceuticals. Under the direction of the authors, Peloton Advantage, LLC (an OPEN Health company), employees Aeja Jackson, PhD, MS, and Eleanor Bush, MA, provided medical writing support and an editor provided editorial support, which were funded by Jazz Pharmaceuticals.

Disclosures: SC Markt, M Whalen, EM Poole, and **JK Alexander** are full-time employees of Jazz Pharmaceuticals, who, in the course of this employment, have received stock options exercisable for, and other stock awards of, ordinary shares of Jazz Pharmaceuticals, plc. **J Polinski, J Kroner,** and **J Shen** are full-time employees of Aetion and hold stock options or equity in Aetion. **VK Somers** is a consultant for Apnimed, Axsome, Eli Lilly, Jazz Pharmaceuticals, and Zoll, and serves on the Sleep Number Scientific Advisory Board.

Results



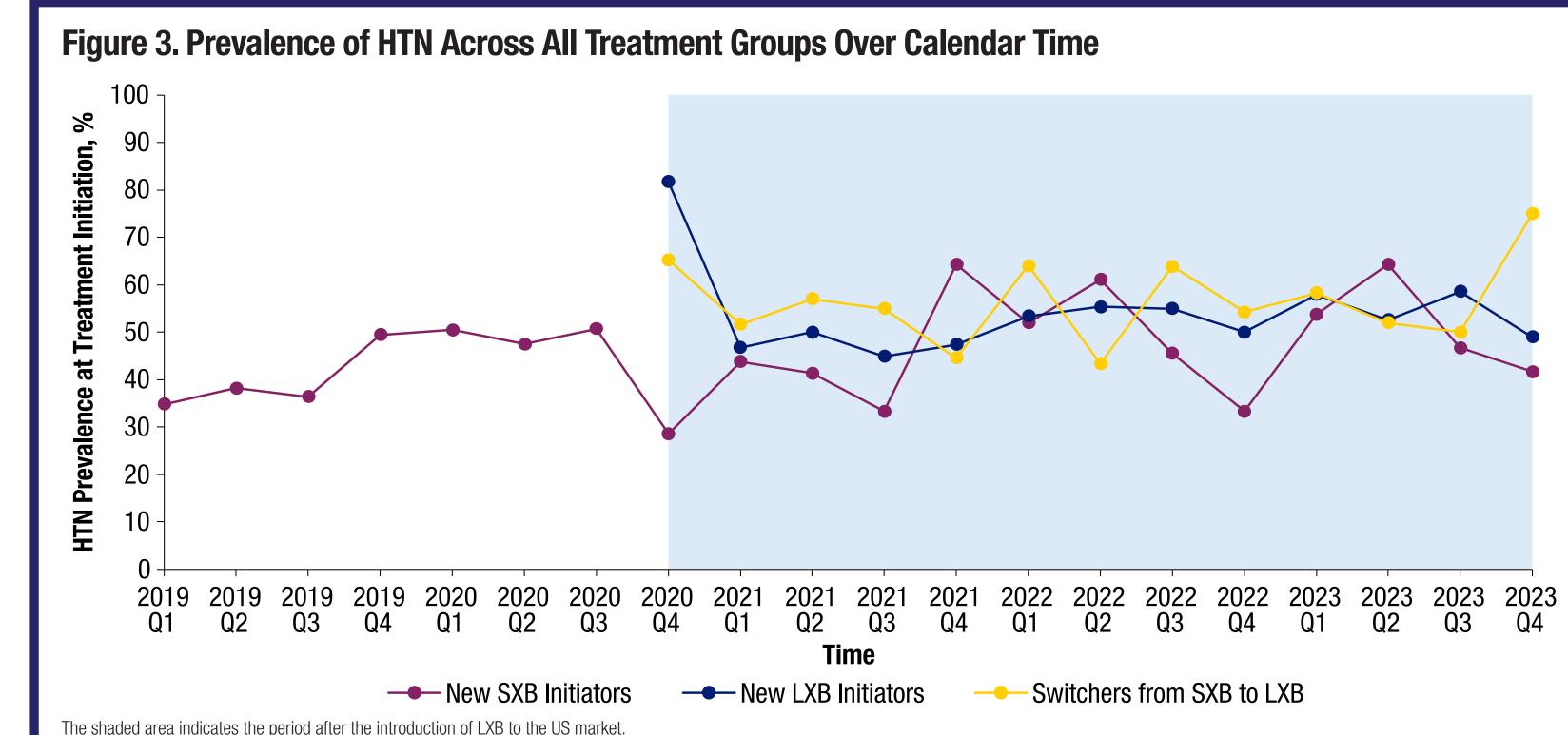
• HTN prevalence increased over time among individuals with narcolepsy and among new and existing SXB users



• Mean age at treatment initiation was 38.1 years in new SXB initiators (n=984) and 40.5 years in new LXB initiators (n=776)

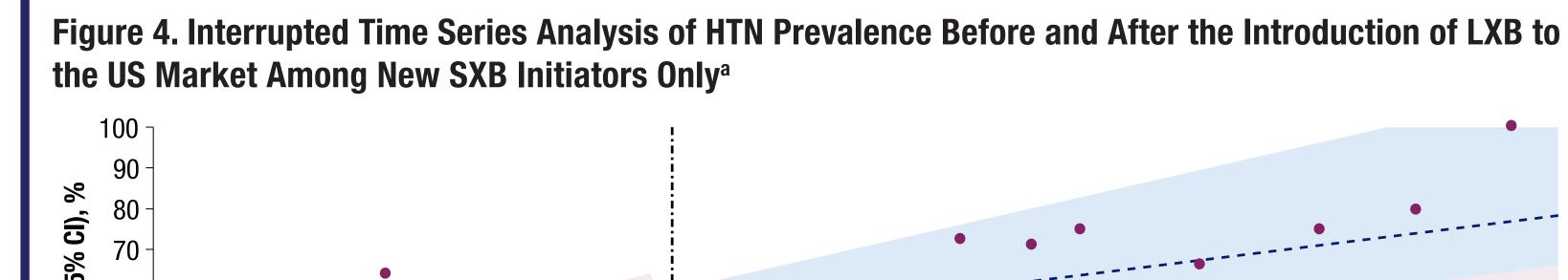


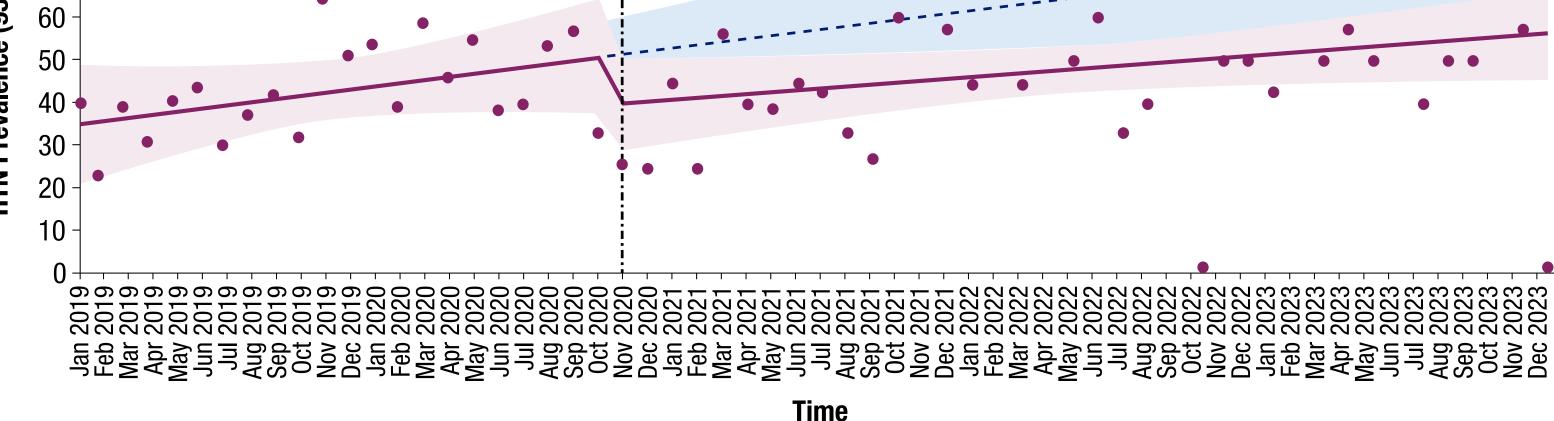
- As LXB initiation increased, a concomitant decrease in SXB initiation occurred; HTN prevalence was high among new SXB initiators prior to LXB approval, and prevalence remained steady in the post-LXB approval period
- Among new SXB initiators, no change in HTN prevalence was observed after the introduction of LXB to the US market, indicating that HTN may not yet be fully recognized or considered in initiation of oxybates
- Limitations of the study include the small sample sizes within each treatment group, as well as limitations common to administrative claims data
- These findings emphasize the need for additional consideration of sodium risks in individuals with narcolepsy due to the high prevalence of HTN in this population seen previously in the literature, 1,10,11 and to the well-established relationship between increased sodium intake and HTN^{5,8}



• Following availability of LXB in the US market, the prevalence of HTN among new initiators of LXB and switchers from SXB to LXB was high (range over time for LXB initiators: 44.9%–81.8%; range over time for switchers from SXB to LXB: 43.4%–75.0%)

• The prevalence of HTN was generally slightly higher in new initiators of LXB and switchers, compared with new initiators of SXB across each quarter; however, the prevalence of HTN among new initiators of SXB did not change substantially after the introduction of LXB to the US market





^aInitiators of branded or authorized generic twice-nightly SXB or once-nightly SXB. The vertical line indicates introduction of LXB to the US market. CI, confidence interval; HTN, hypertension; LXB, low-sodium oxybate; SXB, sodium oxybate.

——— Change in slope

HTN, hypertension: LXB, low-sodium oxybate: Q, quarter: SXB, sodium oxybate

• At LXB introduction to the US market, there was a decrease in HTN prevalence of -4.6% (95% CI: -36.2%, 27.1%) among new SXB initiators

---- Extrapolated trend describing counterfactual scenario

Over the post-LXB approval period, there was no difference in HTN prevalence among new SXB initiators (-0.3% [95% CI: -1.8%, 1.2%])