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Implications of Underreporting Medication Side Effects: Beta-blockers in Heart Failure as a Case Example

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Abstract

Perceiving medication side effects but not reporting them to a clinician is common. Patterns of "under-reporting" and their implications are not well-described. We aimed to address this gap by examining patterns of under-reporting perceived side effects of beta-blockers among patients with heart failure (HF).

In 2016, a survey that evaluated medication-taking behavior was administered to 1114 participants (46.5% response rate) from The Reasons for Geographic and Racial Differences in Stroke (REGARDS) cohort with prior adjudicated HF hospitalization or HF Medicare claim. We examined the results of survey respondents who reported taking a beta-blocker to understand patterns of under-reporting perceived beta-blocker side effects. We defined an under-reporter as a participant who perceived experiencing a side effect from their beta-blocker but did not share it with their clinician (according to survey responses). We conducted a multivariable logistic regression analysis to identify determinants of being an under-reporter. Co-variates included age, sex, race, income, level of education, geographical location, and pill burden. We also examined whether under-reporters differed in self-reported medication adherence and willingness to take additional medication to prevent a future healthcare encounter compared to participants who reported perceived side effects to their clinicians and those who did not experience side effects. Among 310 respondents, 28% (n=87) were under-reporters. Black race (OR 2.11, CI [1.21–3.67]) and education less than college (OR 2.00, CI [1.09–3.67]) were associated with being an

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Author Contributions:

All authors meet the criteria for authorship stated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Dr. Vargas and Dr. Goyal had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Vargas, Levitan, Goyal

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under-reporter. Self-reported medication adherence was similar between groups (under-reporters: 46.3%; those who reported perceived side effects: 49.4%); those did not experience side effects: 45.0%); under-reporters were more frequently unwilling to take additional medication to prevent a doctor's visit (18.9% vs. 12.1% vs. 10.8%), emergency room visit (21.6% vs. 13.3% vs. 9.9%), and hospitalization (17.6% vs. 10.8% vs. 9.0%) compared to the other groups. We conclude that under-reporting perceived side effects of beta-blockers among adults with HF is common, is associated with Black race and low education, and may contribute to patient willingness to take additional medication to prevent future medical encounters.

Keywords

Beta-blocker; side effects; medication adherence

Introduction

Pharmacotherapy is a key pillar of treatment for heart failure (HF). Medications frequently used for HF include diuretics which are critical for decongestion, and neurohormonal antagonists (including beta-blockers) which treat hypertension and combat harmful remodeling effects.[1] Unfortunately, despite the benefits of these medications, adherence to HF treatment remains suboptimal. For example, in a study of 178,000 Medicare beneficiaries, just 52% were considered adherent to HF medication, defined as a medication possession ratio of ≥0.8.[2] An important barrier to medication adherence is the concern about adverse effects.[3] Indeed, if patients are concerned about future adverse effects, or experience a side effect, they may be less likely to continue to take their medication. This is particularly relevant for medications prescribed for HF, such as beta-blockers which can cause myriad side effects including hypotension, dizziness, and bradycardia.[4,5] Reporting side effects to clinicians is important because it provides an opportunity to determine whether a medication is causing the perceived effects, and can facilitate a re-evaluation of the risks and benefits of a given medication. Additionally, an open discussion about medication side effects may strengthen the therapeutic bond between physicians and patients,[6] and facilitate shared decision making. Under-reporting of perceived side effects precludes the opportunity to review and discuss potential side effects, and related shared decision making processes. Accordingly, the phenomenon of under-reporting perceived side effects warrants additional attention.

A prior analysis of a survey completed by adults with HF from the Reasons for Geographic and Racial Differences in Stroke (REGARDS) study revealed that a large proportion of patients report a variety of perceived symptoms related to beta-blocker use including shortness of breath, dizziness, and fatigue; however, a large proportion did not discuss these symptoms with their clinicians.[7] Despite the fact that side effects from various medications are commonly under-reported, the impact of under-reporting side effects on behaviors like medication adherence or willingness to take additional medication is unknown. We sought to address this important knowledge gap by examining the patterns of under-reporting perceived side effects from beta-blockers among patients with HF by

identifying determinants of being an under-reporter, and by exploring medication taking behavior and attitudes among under-reporters.

Methods

In 2016, a survey that evaluated medication-taking behavior was sent by mail to 1114 participants with a prior adjudicated HF hospitalization or Medicare claim for HF from the REGARDS cohort, a longitudinal cohort of Black and White adults from across the continental United States with oversampling of individuals living in the Stroke Belt (Alabama, Arkansas, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee).[8].Among them, 518 (46.5%) completed the survey.[7] We evaluated a subset of this cohort who reported taking beta-blockers (n=310) (Supplemental Figure 1). Of note, although the original REGARDS cohort was developed to study stroke, this cohort of >30,000 participants has been leveraged to study myriad cardiovascular diseases including myocardial infarction and heart failure.[9–12]

Details of the survey have previously been described.[7] Briefly, the survey inquired about the number of prescription medications taken per day, how frequently pills were missed, reasons for not taking medications, and willingness to take additional pills. The survey also inquired about behaviors related to beta-blocker use. Questions asked about participants' perceived side effects related to beta-blocker use ("Have you ever thought that your beta-blocker caused any of the following?"), and whether they had discussed these perceived side effects with clinicians ("Have you ever talked to your doctor, nurse, or other healthcare provider about symptoms related to your beta-blocker?"). The survey listed some of the most commonly reported side effects from beta-blockers including shortness of breath, wheezing, dizziness/lightheadedness, tiredness/fatigue, and impotence.[4,5] Prevalence of these self-reported symptoms were previously reported to range between 6 and 18%.[7]

We classified participants into 3 groups based on whether they experienced and/or reported perceived side effects from beta-blockers. This included: 1) under-reporters, who were defined as participants who perceived experiencing a side effect from their beta-blocker but did not report it to a clinician, 2) participants who reported perceived side effects to a clinician, and 3) participants who did not experience a side effect.

To understand potential determinants of under-reporting, we examined the association between under-reporting and the following variables: age, sex, race, income (≥$35,000 vs. <$35,000 vs. refused to report), education (college degree vs. less than college degree; less than college degree included those who attended college but did not finish, those who finished high school but did not attend college, and those who did not complete high school), geographical location (lives in stroke belt/buckle vs. not), and pill burden (≥5 pills vs. <5 pills). To confirm that predictors were not multicollinear, we calculated variance inflation factors. To understand the potential consequences of under-reporting, we examined patterns of medication adherence across groups. We defined medication adherence as a response of "0 days per month" to the survey question, "In the last month, how frequently did you miss taking at least one of your pills?" We also examined unwillingness toward taking additional medications to prevent a future medical encounter based on a "No" response to any of the

following survey questions: “Would you be willing to take one more pill if A.) It would prevent an unplanned visit to a doctor, nurse, or other healthcare provider? B.) It would prevent an emergency room visit, C.) It would prevent a hospital stay.

For descriptive analyses, we calculated medians with interquartile ranges (IQR) for continuous variables and percentages for categorical variables. To identify key determinants of being an under-reporter, we conducted a multivariable logistic regression. To investigate significant differences between groups with regard to medication adherence and unwillingness to take additional medications to prevent a future medical encounter, we used the Wilcoxon rank sum test and Pearson’s chi-squared test. We used two-sided hypothesis testing with p-value < 0.05 to determine statistical significance. We performed statistical analyses using SAS 9.4 and Stata 14.

Results

Among 310 participants, the median age was 68 years, 50.3% were female, 35.5 % were Black, and 64.5% had an education level less than a college degree. Nearly 50% had heart failure with reduced ejection fraction (defined as an left ventricular ejection fraction of less than 40%), nearly 40% had coronary artery disease, and 21.1% had atrial fibrillation. Twenty-eight percent of the cohort were under-reporters; 30% reported perceived side effects, and 42% did not perceive experiencing side effects (Table 1).

In a multivariable-adjusted logistic regression model, Black race (OR 2.11, CI [1.21–3.67], p = 0.008) and education less than a college degree (OR 2.00, CI [1.09–3.67], p = 0.03) were associated with being an under-reporter (Table 2). Variance inflation factors were all below 1.5, indicating that multicollinearity was not present.

Under-reporters had similar reported medication adherence (46.3%) as those who reported perceived side effects to their clinicians (49.4%) and those who did not experience side effects (45.0%) (p= 0.82). Figure 1 shows participant unwillingness to take additional medication to prevent future medical encounters among under-reporters, those who reported perceived side effects to their clinician, and those who did not experience side effects. As shown, under-reporters were numerically more frequently unwilling to take additional medication to prevent an unplanned medical visit, more frequently unwilling to take additional medication to prevent an emergency room visit, and more frequently unwilling to take an additional medication to prevent a hospital stay compared to those who reported perceived side effects to their clinician, and those who did not experience side effects although this did not reach statistical significance.

Discussion

Our study, based on survey data from the REGARDS national cohort study, highlights a novel concept that we describe here as “under-reporting,” which we defined as the phenomenon of patients perceiving a side effect without reporting this to their clinicians. Our data show that under-reporting is common and has important clinical consequences. In examining adults with HF who take beta-blockers, we found that 1 out of 4 (28%) patients with HF who take beta-blockers may be suffering from a medication-related side

effect unbeknownst to their clinician. This is important for several reasons. First, it suggests that side effects from beta-blockers, a cardiovascular medication that is among the top five most commonly used medications among U.S. adults aged 60–79,[13] may be more common than appreciated. Second, it suggests that clinicians may not be adequately eliciting the necessary data to make informed decisions about continuing medications. Previous work has shown that within primary care encounters, discussions about adverse drug effects and attitudes toward medications are among the least often discussed themes,[14] with some studies suggesting that patients do not ask any questions about their medications in nearly half of their encounters with their primary care physicians.[15] This is important because the lack of discussion about perceived side effects can result in preventable adverse drug events.[16] Indeed, understanding how well a patient is tolerating their medications is critical to evaluating the risk-benefit ratio for pharmacologic agents. Without accurate understanding about whether patients are experiencing side effects, clinicians may be making suboptimal medication decisions.

Under-reporting, or failure to report perceived side effects, additionally precludes investigation into whether the side effect is truly related to the medication. This may be particularly problematic for patients with multiple chronic conditions and polypharmacy —a population in whom symptomatology may be inappropriately ascribed to certain medications with resulting reduction in medication adherence. Although under-reporters did not self-report reduced medication adherence in our study, previous work has shown that self-discontinuation of cardiovascular medications is common—a study assessing medication adherence after a myocardial infarction found that nearly one-third of patients no longer took their prescribed medication after 6 months; notably, perceived side effects were among the most common reasons cited for medication discontinuation.[17] Indeed, individuals with perceived side effects will be among the most likely to self-discontinue their medications. In some cases, self-discontinuation of a medication (often labelled as non-adherence) may be reasonable if in fact the medication is causing unwanted side effects. However, determining this can be quite challenging. Incorrectly ascribing a side effect to a medication and subsequently self-discontinuing that agent can have long-term negative effects on patients' disease control, longevity, and quality of life. Thus, to optimize patient outcomes, open communication between patients and their clinicians about potential side effects is critical. Moreover, review of potential adverse drug events should happen periodically, rather than just at medication initiation.[18] Future strategies should thus include formal processes that can educate patients about possible side effects, quantify potential side effects of medications, and facilitate improved patient-physician communication. Specific strategies could include protocolized checklists to assess for side effects or involvement of a pharmacist.[19] A potentially innovative strategy for identifying side effects (and relatedly, determining medication tolerance) and facilitating improved patient-physician communication could be N-of-1 trials,[20] though this approach remains underdeveloped for this specific purpose to date.

Prior data suggests that reporting perceived side effects to clinicians may build trust between the patient and clinician, and subsequently strengthen the patient-clinician relationship.[6] Thus, under-reporting may preclude opportunities to build trust, which may have important implications on medical decision making. For example, as shown in our study, under-

reporters were more reluctant to take additional medication to prevent future medical encounters. Alternatively, it may be that those who are reluctant to take additional medication may be more likely to under-report perceived side effects. Future studies should further examine this phenomenon, and also determine whether these behaviors translate into higher morbidity and mortality for patients and higher overall healthcare costs. In addition, examining the degree to which under-reporters are interested in deprescribing, an emerging intervention that can potentially reduce the risks of polypharmacy,[21] is yet another area worth exploring further.

Our study also revealed that social determinants of health may be playing a role in under-reporting. Indeed, participants who were Black or had an education less than a college degree were more likely to be under-reporters. The underlying reasons for these observations are not clear. Future qualitative studies that focus on health literacy and attitudes toward the healthcare system may be worthwhile. Moreover, given the myriad of observations about how social determinants of health can negatively impact health outcomes across a range of medical conditions including HF,[22] future studies should also explore whether under-reporting could serve as a potentially novel target to improve outcomes among vulnerable populations.

Our study has several important strengths. First, we examined a diverse patient population, which permitted us to study the role of race on under-reporting. Second, the overall survey response rate was high, which increases generalizability. Our study also had several limitations. First, the sample size precluded a more robust multivariable analysis. Although we included pill burden to account for comorbidity burden, future studies should incorporate specific conditions that may have a direct impact on side effect reporting independent of pill burden. Second, since this study relies on surveys, all data including medication adherence is based on self-report. Notably, patients may not consider self-discontinuation of medication as non-adherence—this could potentially explain the reason that we did not find an association between patterns of side effect reporting and medication adherence. Third, participants who did not respond to the survey were more likely to be Black. Given that Black race was associated with being an under-reporter, it is possible that our findings underestimate the prevalence of under-reporting. Fourth, under-reporting of perceived side effects to clinicians in this study is specific to beta-blockers and does not account for differences in doses or other cardiovascular medications. Fifth, while the study includes questions about willingness to take additional medication to prevent healthcare encounters, there were no questions about rationale. It is also not known whether access to care had a direct impact on under-reporting. For example, participants who live far away from a healthcare facility may experience less frequent interactions with clinicians, reducing opportunity to discuss perceived side effects. Future work should examine the interplay between access of care and discussions about perceived side effects, as well as explore the role of fragmented care[23] on phenomena observed here.

Conclusion

Under-reporting perceived side effects of beta-blockers among adults with HF is common, is associated with Black race and low education, and may contribute to patient reluctance/

hesitation to take additional medication to prevent future medical encounter. This has important implications at the individual patient and physician level, among particular subgroups of patients, and on a population level (those taking beta-blockers). Future work is needed to better characterize the underlying reasons for under-reporting and its impact on outcomes. Moreover, this work supports the need to develop strategies that can effectively elicit perceived side effects from patients, as a means to ultimately improve medication management; especially among Black participants and those with low education attainment.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Conflict of Interest:

Dr. Levitan reports research support from Amgen for observational research related to heart failure treatment, including beta-blockers, and consulting for a research study on heart failure treatment funded by Novartis. Dr. Steinman is supported by National Institute on Aging grants R24 AG064025, K24 AG049057, and P30 AG044281. Dr. Safford reports research support from Amgen,. The other authors report no conflicts. Dr. Goyal is supported by American Heart Association grant 20CDA35310455 and by National Institute on Aging grant K76AG064428; Dr. Goyal receives personal fees for medicolegal consulting related to heart failure; and has received honoraria from Akcea inc and Bionest inc.

Sponsor's Role:

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Key Points

- Among adults with HF, 1 out of 4 patients taking beta-blockers under-report perceived side effects to clinicians.
- Black race and lower education were associated with being an under-reporter.
- Under-reporters were more frequently unwilling to take additional medication to prevent future healthcare utilization compared to others.

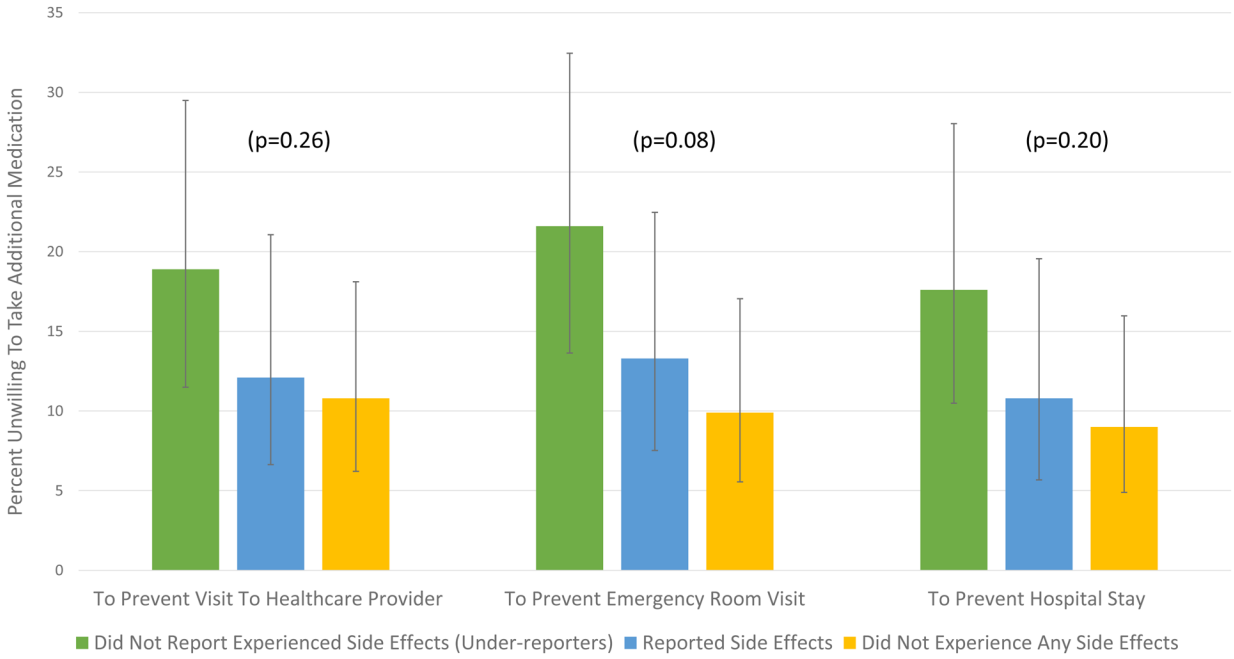

Figure 1: Unwillingness to Take Additional Medication to Prevent Future Medical Encounters

Under-reporters were numerically more frequently reluctant to take additional medication to prevent an unplanned healthcare provider visit, emergency room visit, and hospital stay, compared to those who reported perceived side effects to their providers and those who did not experience side effects although this did not reach statistical significance.

Table 1:

Participant Characteristics Stratified by Perceived Side Effect Reporting Behavior

Characteristics	All	Under-reporters	Reported Perceived Side Effects	Did Not Experience Side Effects	P Value
N	310	87	94	129	
Age ≥65	196 (63.2%)	53 (60.9%)	54 (57.4%)	89 (69.0%)	0.60
Female gender	156 (50.3%)	43 (49.4%)	51 (54.3%)	62 (48.1%)	0.84
Black race	110 (35.5%)	41 (47.1%)	36 (38.3%)	33 (25.6%)	0.007
Income					0.88
≥$35,000	136 (43.9%)	39 (44.8%)	36 (38.3%)	61 (47.3%)	
<$35,000	132 (42.6%)	39 (44.8%)	44 (46.8%)	49 (38.0%)	
Refused	42 (13.5%)	9 (10.3%)	14 (14.9%)	19 (14.7%)	
Education less than college degree	200 (64.5%)	64 (73.6%)	61 (64.9%)	75 (58.1%)	0.04
Lives in stroke belt/buckle	171 (55.2%)	46 (52.9%)	49 (52.1%)	76 (58.9%)	0.61
Pill burden ≥5	248 (80.0%)	67 (77.0%)	78 (83.0%)	103 (79.8%)	0.41
Medical conditions					
HFrEF (EF <40)	56 (49.1%)	22 (50%)	17 (53%)	17 (45%)	0.77
Coronary heart disease	121 (39.8%)	44 (47.3%)	30 (34.9%)	47 (37.6%)	0.19
Atrial fibrillation	64 (21.1%)	29 (31.2%)	15 (17.9%)	20 (15.9%)	0.016
Hypertension	215 (69.4%)	70 (74.5%)	63 (72.4%)	82 (63.6%)	0.17
Diabetes	94 (30.9%)	29 (31.5%)	24 (27.9%)	41 (32.5%)	0.76

Table 2:

Association Between Participant Characteristics and Under-Reporting of Perceived Side Effects

Characteristics	Unadjusted Odds Ratio	Adjusted Odds Ratio
Age ≥ 65 years old	0.87 [0.52,1.45]	1.07 [0.62,1.86]
Female gender	0.95 [0.58,1.56]	0.88 [0.52,1.49]
Black race	1.99 [1.20,3.31]	2.11 [1.21,3.67]
Income < $35,000	1.00 [0.60,1.67]	0.69 [0.38,1.26]
Education less than college degree	1.78 [1.03,3.08]	2.00 [1.09,3.67]
Lives in stroke belt/buckle	0.88 [0.54,1.45]	0.89 [0.53,1.49]
Pill Burden ≥ 5	0.78 [0.43,1.42]	0.75 [0.40,1.41]