Retrospective Evaluation and Analysis of Pharmacoequity with Guideline-directed Medical Therapy in Heart Failure with Reduced Ejection Fraction (REAP-HF)

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Abstract

Introduction: Patients with heart failure with reduced ejection fraction (HFrEF) who are optimized on guideline-directed medical therapy (GDMT) have improved outcomes; however, medication access and affordability are potential barriers to achieving pharmacoequity. This study sought to compare rates of HFrEF GDMT prescribing at hospital discharge across prescription insurance status groups. *Methods:* This was a single-center, retrospective cohort study of adult HFrEF patients. Patients were grouped according to prescription insurance status. The primary outcome was the percentage of HFrEF patients prescribed quadruple GDMT at hospital discharge. Key secondary outcomes included the presence of contraindications to therapy and 30-day all-cause readmission rates. The study was approved by the Institutional Review Board at the University of Tennessee Health Science Center. *Results:* Among the 200 included patients, 63% were male and 92% were black. Discharge on quadruple GDMT across insurance groups was 18% for Medicare Part D, 24% for Medicaid, 24% for commercial, and 33% for uninsured. There was no difference between insurance groups in rates of prescribed quadruple GDMT at hospital discharge (p=0.302) or 30-day hospital readmission (p=0.665). Additionally, there was a significant increase in the number of uninsured patients on quadruple GDMT after hospitalization compared to pre-hospitalization (13% vs 33%, p=0.002). Eighty percent of all patients had a contraindication to at least one GDMT agent. *Conclusion:* There was no difference in rates of prescribed quadruple GDMT at hospital discharge based on insurance status. However, this study did elucidate the impact of medication access programs improving pharmacoequity in the uninsured patient population.

Keywords: Guideline-directed medical therapy – Insurance - Pharmacoequity – Heart Failure – Medication access

Introduction

Pharmacoequity aims to ensure that all patients, regardless of race, ethnicity, socioeconomic status, and available resources, have access to the highest quality medications.[1] Inequities in access and affordability of prescription drugs are well documented, with racial and ethnic minority groups experiencing greater disparities in care.[2] Patients with heart failure with reduced ejection fraction (HFrEF) optimized on guideline-directed medical therapy (GDMT) have improved outcomes, including reduced morbidity and mortality.[3–9] The 2022 American Heart Association (AHA) guidelines recommend quadruple GDMT (quad-GDMT) with an angiotensin receptor/ neprilysin inhibitor (ARNi), beta blocker (BB), mineralocorticoid receptor antagonist (MRA), and sodium-glucose cotransporter-2 inhibitor (SGLT2i) for patients with HFrEF.[10] The current AHA guideline recommendations do not offer guidance on the timing of initiation of quadruple therapy; however, the American College of Cardiology recently published decision pathway that encourages the simultaneous initiation and titration of more than one therapy, as appropriate.[10,11] While recent studies have shown that most patients with HFrEF are eligible for quadruple therapy at discharge, strategies relying on initiation of quadruple therapy at outpatient follow-up have not been shown to improve mortality or rates of rehospitalization.[12–14] In patients eligible for GDMT at hospital discharge, cost and access to beneficial medications remain a barrier, especially with ARNi and SGLT2i.[11]

Several factors influence the cost associated with obtaining these medications. Approximately 13% of Americans do not have prescription health insurance.[15] Different insurance systems exist for patients to obtain, with Medicare, Medicaid, and commercial insurance plans being widely available. Each of these systems have varying prescription drug coverage and costs associated. High out-of-pocket costs or copays significantly decrease medication adherence rates in patients with HFrEF.[16] There are limited studies that compare prescription insurance status and its impact on pharmacoequity in HFrEF patients.[17,18] The purpose of this study was to evaluate pharmacoequity in patients with HFrEF by assessing GDMT prescribing at hospital discharge based on prescription insurance status.

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Methods

Design Overview

This was a single-center, retrospective cohort study of patients admitted between May 1, 2022, and November 30, 2023, for a primary diagnosis of heart failure (HF). Patients were identified using a diagnosis-related group report that included all HF admissions. Individual patient data points were collected from the Cerner Millennium® electronic medical record (EMR). The Institutional Board of Review at the University of Tennessee Health Science Center approved this retrospective review.

Patient Selection

Eligible patients included those older than 18 years with documentation of left ventricular ejection fraction (LVEF) less than or equal to 40% verified through echocardiogram during admission visit or within one year prior to admission. Exclusion criteria included end-stage kidney disease (ESKD), federal prescription insurance (Veterans Affairs), in-hospital mortality, discharge to a skilled nursing facility, rehabilitation center, or hospice, and New York Heart Association (NYHA) class I functional status per provider documentation, if available. For analysis, patients were grouped according to prescription insurance status: Medicare Part D, Medicaid, commercial insurance, and uninsured.

Outcomes

The primary outcome was to determine the percentage of HFrEF patients prescribed quad-GDMT at hospital discharge. Key secondary outcomes included the percentage of ARNi and SGLT2i prescribing rates at hospital discharge, 30-day all-cause readmission rates, and the presence of any contraindication to any component of quad-GDMT. Relative and absolute contraindications or adverse effects consisted of the presence of acute kidney injury (AKI) during admission, hypotension or bradycardia within 48 hours of hospital discharge, serum potassium level greater than 5 mmol/L during the hospital admission, and a documented history of angioedema. Additional data points included the medications prior to hospital admission and completion of a prior authorization (PA).

Study Definitions

Quad-GDMT was defined as ARNi (sacubitril/valsartan), beta blocker (bisoprolol, carvedilol, and metoprolol succinate), MRA (spironolactone or eplerenone), and SGLT2i (dapagliflozin or empagliflozin). If ARNi use is not feasible, the utility of any medication in the angiotensin-converting enzyme inhibitor (ACEi) or angiotensin II receptor blocker (ARB) classes was an acceptable alternative.[10] Dapagliflozin and empagliflozin were a part of a discounted outpatient formulary via a qualifying 340B drug pricing program utilized at the study site outpatient pharmacy. Additionally, the study site has specialized pharmacy technicians available to complete PAs for ARNi or SGLT2i. On November 1, 2023, Tennessee Medicaid removed the PA requirement for SGLT2i therapy.

NYHA Class I functional status is defined as having no symptoms or limitations in ordinary physical activity and was evaluated by EMR documentation.[10] ESKD was defined as receiving dialysis before or during admission or eGFR < 15 mL/min/1.73 m^2, as reported in medical records in the previous year.[19] AKI was defined as an increase in serum creatinine (SCr) greater than or equal to 0.3 mg/dL within 48 hours or an increase in SCr greater than or equal to 1.5 times baseline, known or presumed to have occurred within the prior seven days.[20] Hypotension was a systolic blood pressure of less than 90 mmHg, and bradycardia was a heart rate of less than 60 beats per minute.

Data and Statistical Analysis

Descriptive statistics were done using the SPSS statistical program version 29.0 for Windows (SPSS, Inc., Chicago, IL). Frequencies were reported as the number of cases with the evaluated outcome divided by the total number of patients (N, %). Continuous data was reported as median (25%-75% interquartile range). When comparing patient outcomes, continuous data was analyzed using analysis of variance (ANOVA), and categorical data was analyzed using chi-square tests with a Bonferroni correction. All p-values < 0.05 were considered statistically significant.

Results

Study Population

Five hundred and sixty-one patients were screened with a total of 200 patients meeting the criteria for inclusion. The most common reasons for exclusion were ESKD, not admitted for a primary diagnosis of HFrEF, and not discharged to home. There were 108 patients in the Medicare group, 41 patients in the Medicaid group, 21 patients in the commercial group, and 30 patients in the uninsured group.

Baseline characteristics were balanced between groups (**Table 1**). Sixty three percent of included patients were male and 92% percent were black with a median age of 63 years (IQR, 54-70). Patients in the Medicare group had a higher median age compared to patients in the other insurance groups (p<0.001). Before hospital admission, 16% of patients were on quad-GDMT and there was no difference between groups (p=0.363). The median hospital length of stay was 4.1 days (IQR, 2.8-6.0), and the cardiology inpatient service was consulted in about half of all patient encounters.

Outcomes

For the primary outcome, there was no difference in quad-GDMT at discharge across insurance groups. Twenty-two percent of all patients were discharged on quad-GDMT, and 55% of patients who were discharged on quad-GDMT were on quad-GDMT prior to hospitalization. Most patients were discharged with a median of two (IQR, 2-3) of the four components of quad-GDMT, with BB being the most utilized class followed by a SGTL2i. Thirty-three percent of uninsured patients, 24% of both Medicaid and commercially insured

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patients, and 18% of Medicare patients were discharged on quad-GDMT (p=0.302) **(Table 2)**.

Compared to pre-hospitalization, rates of quad-GDMT at hospital discharge increased across all insurance groups, although not statistically significant (**Figure 1**). There was a significant increase in the number of uninsured patients on quad-GDMT after hospitalization compared to pre-hospitalization (13% vs 33%, p=0.002). There was a 240% increase in SGLT2i prescriptions in this subgroup from pre-admission to discharge. Comparatively, there was a 75% increase in ARNi prescriptions at hospital discharge for uninsured patients.

There was no difference between insurance groups in rates of prescribing of ARNi (p=0.221) and SGLT2i therapy (p=0.083). More patients received an SGTL2i at hospital discharge compared to an ARNi (34% vs 26%, respectively). Seven patients, all in the Medicaid group, required a PA to be completed during the admission visit for an ARNi or SGLT2i. The study site outpatient pharmacy was utilized for 37% of Medicare patients, 59% of Medicaid patients, 38% of commercial patients, and 87% of uninsured patients (p=0.05).

A total of 19% of patients were readmitted for any cause within 30 days of hospital discharge. All-cause readmission rates did not vary based on insurance group (p=0.665). Furthermore, there was no difference in readmission rates for patients discharged on quad-GDMT compared to those not discharged on quad-GDMT (18.2% vs 18.6%, respectively). Absolute and relative contraindications or adverse effects to GDMT agents were common, as 63% of all patients had at least one to any agent. Notably, 52% of the patients who were discharged on quad-GDMT (n=44) had at least one contraindication or adverse effect to any of the four medication classes. The most common contraindication to ARNi/ACEi/ARB/MRA initiation was AKI, with 51% of all patients experiencing an AKI during the hospital stay. Within 48 hours of discharge, 12% of patients experienced hypotension-possible contraindication to all components of quad-GDMT-, and 6% of patients experienced bradycardia-contraindication for BB. Incidence of hyperkalemia, adverse effect for ARNi/ACEi/ARB/MRA, and a history of angioedema, contraindications for ARNi/ACEi, were infrequent in the study population, at 8% and 6%, respectively.

Discussion

In this study, there was no difference in prescribing quad-GDMT at hospital discharge based on insurance status. Of note, 22% of all patients were discharged on quad-GDMT, representing a potential opportunity to identify strategies to improve adherence to guideline recommendations. Comparatively, analysis from the Get With The Guidelines-Heart Failure registry found that only 9% of Americans were on guideline-directed treatment, and this data was collected prior to the addition of an SGLT2i as a Class I recommendation.[10,21] Consequently, the current study achieved more than twice the national average in quad-GDMT attainment.

Recent data suggests that mortality rates for HF patients have increased, with mortality rates greater than twenty years ago despite advancements in GDMT with known mortality reducing benefit.[22] In a study published this year by Tang et al, implementation of quad-GDMT globally resulted in almost 1.2 million (95% CI, 767,933-1,914,561) lives saved in a 12-month period, largely by prevention of cardiovascular mortality.[23] In the United States, black patients with HF have an increased risk of mortality as compared to white patients.[24] Ninety two percent of enrolled patients were black, emphasizing the heightened significance of achieving pharmacoequity in this demographic due to higher risk of negative outcomes, including death. Furthermore, lower socioeconomic status is associated with an increased risk of mortality and hospital readmission.[25–28] Social determinants of health impact medication access and adherence, affecting patient morbidity and mortality.

A recent cross-sectional pricing analysis of online discount card programs found that the 30-day cost of triple therapy with generic BB/ACEi/MRA regimen was $10.58 compared with guideline-recommended quad-GDMT of ARNi/BB/MRA/SGLT2i, which was priced at over $1,400.[29] Shanklin et al. demonstrated that strategies that rely on inpatient initiation of GDMT may be successful in increasing medication access through the utilization of pharmacists and other specialized personnel to complete PAs and identify coverage gaps.[30] At the study site, the clinical pharmacy team works extensively alongside the pharmacy technician specialists in medication access to ensure patients have access to GDMT as able, attempting to overcome any prescription barriers patients may have prior to hospital discharge. This information is well-documented in the patient's chart in order to facilitate communication of this information to all care team members.

One unique finding of this study was that uninsured patients were most likely to be on quad-GDMT at hospital discharge compared to other insurance groups, and there was a significant increase in the number of uninsured patients discharged on quad-GDMT. The rise in SGLT2i prescriptions mainly drove the increase in quad-GDMT in the uninsured group, specifically as 87% of uninsured patients received discharge prescriptions from the study site outpatient pharmacy via the discount formulary. Utilization of a 340B drug pricing program has been identified as one strategy to enhance medication access and affordability for targeted vulnerable patient populations.[11]

However, those with prescription insurance with high copays or out-of-pocket costs are still presented with affordability concerns that cannot be alleviated via discount prices. The benefit of the discount formulary was elucidated in this study as 52% of uninsured patients were discharged on an SGLT2i

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compared to 21% of patients who were discharged on an ARNi, a brand product not available on the discount formulary. Access to ARNi can be increased via the utility of coupon cards and patient assistance programs. Hospitals can ensure staff, including case management, social work, pharmacy, and providers, have education pertaining to available programs and steps patients need to take to ensure access to medications prior to discharge.[11]

Previous studies have evaluated GDMT at hospital discharge. Davogustto et al. and Tran et al. assessed ARNi use in Medicare, Medicaid, commercially insured, and uninsured HF patients. Both studies found that having insurance was associated with more ARNi discharge prescriptions, and uninsured patients had a significantly lower likelihood of ARNi discharge prescriptions.[17,18] Our study is unique from other studies because quad-GDMT at discharge was assessed across multiple prescription insurance plans and in patients without insurance. Unlike these studies, we did not detect a difference in the prescribing of quad-GDMT at hospital discharge, and though not significant, uninsured patients had the highest rates of discharge GDMT.

Hesitation to initiate quad-GDMT in the inpatient setting was likely associated with the high incidence of acute and chronic renal dysfunction in the patient cohort. Over 50% of the population had an AKI during hospitalization, and 60% of patients had CKD stage 3-4. D'Amario and colleagues have also evaluated eligibility for GDMT, and authors found that 46% of patients were eligible for quad-GDMT based on the 2021 European Society of Cardiology Guidelines on Heart Failure.[14] In the D'Amario study, 13% of patients had significant renal dysfunction, which was defined as an eGFR < 30 mL/min/1.73m^2, and renal insufficiency was found to be a predictor of use of less than two GDMT agents at hospital discharge (adjusted odds ratio (OR) [95% confidence interval (CI)], 0.16 [0.08-0.32]).[14,31]

Our study only evaluated one clinical outcome, which was 30-day readmission rates. All-cause hospital readmission rates did not vary for patients discharged on quad-GDMT compared to those not discharged on quad-GDMT. While this finding is inconsistent with previous evidence that has shown the ability of GDMT agents to reduce HF hospitalizations over a long follow-up period, the low sample size and the study's retrospective nature limits the ability to draw conclusions regarding the effect of quad-GDMT on readmissions rates.[10]

Our study has several limitations, including a small sample size, unbalanced study groups, single-center retrospective study design, reliance on proper charting in the EMR, and an inability to account for all the reasons why a provider chose not to prescribe agents at discharge. Several factors may also limit the generalizability of our findings, including the institution's available resources and patient population. This study was conducted at an institution with a 340B drug pricing program and specialized pharmacy technicians who assist in prior authorizations, without these resources, discharge prescriptions would likely be different for uninsured and commercially insured patients. This study took place in a city with a predominantly Black community. However, eligibility for quad-GDMT does not vary by race per guideline recommendations.

The 2022 HFrEF guidelines do not expressly detail an order of addition for GDMT agents or if all agents should be initiated simultaneously. For this reason, some providers may not have elected to prescribe all GDMT medication classes at discharge. Additionally, this study did not analyze patient compliance with therapy after discharge, which is an important factor in determining the effects of these medications on reducing hospitalizations and mortality. The generalizability of this study is limited by the institution's available resources. Despite these limitations, our study is the first to review how pharmacoequity for patients with HFrEF may be impacted by access to hospital resources, including the 340b drug pricing program.

Conclusion

In this retrospective review, prescription health insurance status did not affect rates of discharge quad-GDMT in patients with HFrEF, with approximately 1 in 4 patients being discharged on quad-GDMT. Compared to pre-hospitalization, prescribing of quad-GDMT at hospital discharge increased numerically across all insurance groups. The uninsured population had the greatest increase in quad-GDMT prescribing with several institutional factors contributing, including hospital outpatient pharmacy, pharmacy medication access team, and a discounted drug pricing programs. Further studies are needed to identify barriers to initiation of quad-GDMT and impact of utilization of health-system outpatient pharmacy on adherence post-hospital discharge.

Author Contributions

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Conflicts of Interest

The authors do not have any conflicts to disclose.

Disclaimer

The statements, opinions, and data contained in all publications are those of the authors.

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Table 1. Baseline Characteristics

Baseline Characteristics					
	Medicare (n=108)	Medicaid (n=41)	Commercial (n=21)	Uninsured (n=30)	p-value
Age, years – Median (IQR)	68 (62-74)	57 (47-61)	54 (48-72)	58 (51-63)	< 0.001
Male	64 (59)	29 (71)	13 (62)	20 (67)	0.597
Black Race	97 (90)	39 (95)	20 (95)	27 (90)	0.697
Allergies to GDMT	6 (6)	1 (2)	0 (0)	0 (0)	0.342
History of Angioedema	10 (9)	1 (2)	1 (5)	0 (0)	0.177
New-Onset Heart Failure	6 (6)	1 (2)	1 (5)	3 (10)	0.587
Ejection Fraction, %, Median (IQR)	25 (20-30)	25 (20-30)	25 (25-36)	20 (19-25)	0.501
Stage 3-4 CKD	45 (42)	15 (37)	5 (24)	5 (17)	0.052
COPD	32 (30)	13 (32)	6 (27)	8 (27)	0.974
Hypertension	103 (95)	39 (95)	21 (100)	25 (83)	0.049

All results are presented as n (%) unless stated otherwise.

CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; GDMT = Guideline-Directed Medical Therapy; IQR = interquartile range.

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Table 2. Discharge Quad-GDMT Prescribing Across Insurance Groups

Primary Outcome	Medicare (n=108)	Medicaid (n=41)	Commercial (n=21)	Uninsured (n=30)	p-value
Discharge Quad-GDMT	19 (18)	10 (24)	5 (24)	10 (33)	0.302
Discharge Quad-GDMT Breakdown Across Insurance Groups					
ARNi/ ACEi/ ARB	63 (58)	25 (61)	16 (76)	22 (73)	0.259
BB	93 (86)	36 (88)	17 (81)	28 (93)	0.606
MRA	37 (34)	15 (37)	6 (29)	15 (50)	0.367
SGLT2i	53 (49)	29 (71)	14 (67)	17 (57)	0.083

All results are presented as n (%) unless stated otherwise.

ARNi = Angiotensin Receptor/ Nephrilysn Inhibitor; ACEi = Angiotensin Converting Enzyme Inhibitor; ARB = Angiotensin Receptor Blocker; BB = Beta Blocker; GDMT = Guideline-Directed Medical Therapy; MRA = Mineralocorticoid Receptor Antagonist; SGLT2i = Sodium-Glucose Cotransporter-2 Inhibitor.

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Figure 1. Quad-GDMT Prescribing from Admission to Discharge Across Insurance Groups