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Describing antipsychotic prescribing patterns in outpatients with Alzheimer's disease using national survey data

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Purpose: Antipsychotics can increase risk of death in older adults with dementia-related psychosis treated with atypical antipsychotic drugs. In 2012, the Centers for Medicare and Medicaid Services (CMS) instituted a still-ongoing national initiative to reduce antipsychotic prescribing in older adults with dementia residing in nursing homes. The purpose of this study is to describe the potential impact of this initiative on prescribing patterns of antipsychotics and potential substitute psychotherapeutic medications in older adults residing in the community.

Methods: We conducted a cross-sectional analysis of an outpatient survey of office visits from the National Ambulatory Medical Care Service (NAMCS) between 2010-2015. NAMCS is a nationally representative database that measures outpatient healthcare utilization and includes medications prescribed in physician offices. Data is available at the physician-visit level; individual patients may be responsible for more than one visit. Patients with dementia (n=1032) were identified using ICD-9-CM diagnosis codes (290. 0, 290. 1x, 290. 2x, 290. 3, 290. 4x, 291. 2, 292. 82, 294. 1x, 294. 2x, 331. 0, 331. 1x, 331. 2, 331. 82), anti-dementia medications (memantine, donepezil, rivastigmine, galantamine), and physician self-report of dementia as a pre-existing condition. Demographic characteristics of patients included age at visit, sex, race/ethnicity, and source of payment. Provider characteristics included provider type and specialty. For each visit, we identified prescribing of the following psychotherapeutic medication classes: antipsychotics, opioids, benzodiazepines, non-benzodiazepine receptor agonists, and antidepressants. We describe trends in proportion of visits among patients with a dementia diagnosis and psychotherapeutic medication use before (2010-2011) and during (2012-2015) the CMS Initiative and compared their rates to the overall population. We grouped survey years in two-year increments (2010-2011, 2012-2013, 2014-2015) per NAMCS recommendation to produce reliable annual visit rate estimates. Proportions and chi-square statistics were calculated using SAS 9. 4 enterprises software.

Results: Between 2010-2015, there were an estimated 5,722,572,891 (n= 267,346) outpatient physician visits of US adults; of these, 24,938,691 (n=1,032) involved dementia. Most dementia-related visits were among Medicare Beneficiaries (77%). Their average age was between 76-85 years old, 64% were female, and 56% were white. Relative to the overall outpatient-visit population, dementia-visits had higher proportions of prescriptions for antipsychotics compared to the overall-population visits (3. 2% vs. 0. 5%). Higher prescription rates among dementia-related visits were also seen for opioids (8. 1% vs. 3. 3%), antidepressants (18. 2% vs. 4. 2%), and benzodiazepines (6. 3% vs. 1. 9%). Both cohorts had low rates of non-benzodiazepine receptor agonist prescribing (0. 6% vs. 0. 1%). Despite CMS' initiative to reduce antipsychotic use in the nursing homes, outpatient prescribing rates continued to rise after 2012, from 0. 18% in 2010-2011 to 2. 85% between 2014-2015.

Conclusion: Our findings indicate that in the outpatient setting, older adults with dementia are favored when it comes to psychotherapeutic medication prescribing. As well, our descriptive study does not find evidence that the CMS Initiative impacted antipsychotic prescribing in older adults residing in the community. Indeed, antipsychotic exposure remain common in the outpatient setting, which may increase risk of mortality and other adverse effects in this population. The use of antipsychotics and other psychotherapeutic medications in community-dwelling older adults - and the potential impacts of such use - requires further investigation.

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Comparison of Glycemic Control Pre and Post-Treatment of Hepatitis C in a Veteran Population with Type 2 Diabetes Mellitus

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Purpose: There is evidence to suggest an association between Hepatitis C (HCV) infection and type 2 diabetes mellitus (T2DM). In a new era of treatment with interferon-free HCV regimens it is possible to assess the effect of HCV therapy on glycemic control without the confounding effects of interferon alfa-2b, which has the potential to alter glycemic control. The primary objective is to report the change in hemoglobin A1C with interferon-free HCV regimens in patients with T2DM within the Veterans Affairs Maryland Health Care System (VAMHCS). The secondary objective is to report the change in T2DM medication regimens and dosages.

Methods: A pharmacy student conducted a retrospective chart review at the VAMHCS from January 1, 2014 to January 1, 2018. Patients were included if they had T2DM and have completed treatment at a VAMHCS HCV clinic with an interferon-free HCV treatment regimen (daclatasvir/sofosbuvir, elbasvir/grazoprevir, ledipisvir/sofosbuvir, ombitasvir/paritaprevir/ritonavir/dasabuvir, sofosbuvir/ribavirin, sofosbuvir/velpatasvir) and achieved sustained virologic response for 12 weeks (SVR 12). The following baseline data points was collected: age, sex, race, weight, active alcohol use, location of the HCV clinic, hemoglobin A1C, HCV genotype, presence or absence of cirrhosis (compensated or decompensated if present), quantitative HCV RNA viral load, HCV treatment regimen, any history of interferon or protease inhibitor use within the past year, and the presence or absence of SVR 12 after treatment completion. Hemoglobin A1C as well as T2DM medication class and an increase, decrease, or no change in dose was recorded at baseline and at 3, 6, and 18 months post HCV treatment initiation. Data was analyzed using Microsoft Excel 2010. A paired sample t-test was used to analyze the data collected.

Results: 601 patients have been identified who meet the inclusion criteria. A preliminary review of 31 randomly selected patients showed no significant change in either average hemoglobin A1C or number of medications to treat T2DM between patients at baseline and 3, 6 or 18 months post HCV treatment initiation. In the 14 patients with a baseline hemoglobin A1C greater than or equal to 7, there was a trend towards decreased hemoglobin A1C from baseline to 3, 6, and 18 months post HCV treatment initiation. The average number of T2DM medications showed an overall increase from baseline to 3, 6, and 18 months in all patients as well as in the patients with a baseline hemoglobin A1C greater than or equal to 7.

Conclusion: The average hemoglobin A1C and number of T2DM medications did not show any significant change from baseline to 3, 6 or 18 months in this preliminary analysis. In a subgroup analysis of patients with baseline hemoglobin A1C greater than or equal to 7 there is a trend towards decreased hemoglobin A1C after 3, 6, and 18 months post HCV treatment initiation. Further analysis is ongoing to identify and evaluate additional trends and the potential significance in this population.

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Prevalence and medication safety concerns regarding contrast induced acute kidney injury at Frederick Memorial Hospital

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Purpose: The use of contrast has been associated with acute kidney injury (AKI) and hence termed Contrast-Induced Acute Kidney Injury (CI-AKI). CI-AKI has been linked to prolonged hospitalization, adverse health outcomes, and increased healthcare cost. CI-AKI is the third leading cause of kidney injury in the hospital setting. Therefore, contrast use at Frederick Memorial Hospital (FMH) must be reviewed to ensure safety. The first objective is to determine the prevalence of CI-AKI at FMH. The second objective is to evaluate the safe use of contrast at FMH by assessing the medication use process and by performing gap analysis.

Methods: The Kidney Disease Improving Global Outcomes (KDIGO) defines AKI as an increase in serum creatinine (SCr) greater than or equals to 0.3mg/dl within 48 hours or an increase in SCr greater than or equals to 1.5 times baseline within 7 days or 25 percent increase of SCr from baseline or Urine output less than 0.5ml/kg/h for 6 hours. Some of the significant risk factors for CI-AKI include age greater than or equals to 65 years, patient's pre-existing renal disease, hypertension, diabetes mellitus, heart failure, metabolic syndrome, concurrent nephrotoxic medications, and anemia.

In obtaining the first objective, a search within the electronic medical record between January and June 2018 for imaging procedures that required contrast agents was performed. This search yielded 4070 imaging procedures that needed contrast. The sample was randomized using excel to extract 150 patients. A chart review of the 150 patients was conducted to determine the prevalence of CI-AKI at FMH.

In obtaining the second objective, a gap analysis was conducted per FMH's existing policy and procedures. The process of procurement, storage, prescribing, verification, dispensing, administration and monitoring of contrast agents at FMH was assessed for gaps and opportunities for improvements.

Results: Out of the 150 charts that got reviewed, 55.3 percent of the patients met KDIGOs definition of CI-AKI. 36 percent of the patients did not meet the definition of CI-AKI, while we were unable to assess the presence or absence of CI-AKI in 8.7 percent of the patients. Seventy percent of patients with CI-AKI had one or more significant risk factors present, 53 percent of patients with CI-AKI were greater than or equals to 65 years, and 54 percent of patients with CI-AKI were also on a nephrotoxic medication.

Our gap analysis showed that patient screening and medication reconciliation process have the lowest success rate (29 percent) followed by the prescribing and monitoring (36 percent). Contrast procurement had a success rate of 92 percent. Contrast administration had a success rate of 75 percent.

Conclusion: From the data result presented, there is a significant prevalence in AKI resulting from the use of contrast, and patients with the risk factors are at a high probability of having CI-AKI after the use of contrast. There are opportunities for improvement in the medication use process of contrast at FMH especially in the aspect of prescribing, patient evaluation, medication reconciliation and patient counseling. Improving the medication use process will help identify and treat patients that are at high risk of having unwanted outcomes including CI-AKI from the use of contrast.

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Safety evaluation of sacubitril/valsartan in acutely decompensated heart failure

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Purpose: Data on the safety of sacubitril/valsartan in patients presenting with acute decompensated heart failure (ADHF) are lacking. Acute decompensated heart failure is commonly associated with hypotension and acute kidney injury (AKI), and both adverse effects could be exacerbated by sacubitril/valsartan. The objective of this study was to compare the rates of hypotension and AKI when continuing or discontinuing sacubitril/valsartan for heart failure patients in the setting of ADHF at a large academic medical center. We hypothesized that patients with ADHF who were continued on sacubitril/valsartan on admission would experience higher rates of hypotension and AKI compared to those who did not receive sacubitril/valsartan.

Methods: This was a retrospective cohort study of patients with ADHF, who were admitted to a large academic medical center. The retrospective data were collected from electronic health records. We included individuals admitted between February 2016 and January 2018, who were at least 18 years of age, had heart failure with reduced ejection fraction, New York Heart Association (NYHA) functional class II-IV, presumed ADHF at admission, and a history of sacubitril/valsartan use immediately prior to admission. Those with concomitant use of sacubitril/valsartan and ACE inhibitors or angiotensin receptor blockers were excluded. The primary endpoints for this study included percent change in serum creatinine at discharge and rate of hypotension (presence of at least 1 hypotensive episode, defined as < 90/60 mm Hg). The secondary outcomes studied included percent weight change at discharge, percent creatinine clearance (CrCl) change at discharge (using the Cockcroft-Gault equation), percent change to lowest systolic blood pressure (SBP), number of hypotensive occurrences, time to first hypotensive episode, and length of hospitalization. Descriptive statistics were used to summarize the results; categorical variables were presented numerically or as percentages while continuous variables were presented as means with standard deviations. Student t-test was used for continuous variables and chi-square test for nominal values.

Results: A total of 24 patients were included in this study: 17 patients (70.8%) were continued on sacubitril/valsartan upon admission (continued group), and 7 patients (29.2%) were discontinued (discontinued group). While both groups had an average left ventricular ejection fraction (LVEF) of approximately 21%, the discontinued group had more patients with severe heart failure (28.6% had NYHA functional class IV) whereas the continued group had none. Chronic kidney disease was identified in 7 patients (41.2%) in the continued group, compared to 6 patients (85.7%) in the discontinued group. Inotrope use was more common in the discontinued group (4 patients (57.1%) vs. 7 patients (41.2%)).

The primary and secondary outcomes from this study are reported in **Table 1**. The incidence of AKI at baseline was higher in the discontinued group (6 patients (85.7%)) compared to the continued group (5 patients (29.4%)). The average serum creatinine at admission in the continued group was 1.37 compared to 2.16 in the discontinued group. The discontinued group had a significant serum creatinine recovery at 72 hours **(Figure 1)** and at discharge. The continued group had a modest percent change in serum creatinine (-2.95 vs. -39.84; p=0.0019) and CrCl (-4.66 vs. 22.99; p=0.0005) at discharge, which demonstrated a significant recovery in renal function for the discontinued group. There was no significant difference in hypotensive occurrence throughout admission. However, the percent decrease in blood pressure from baseline to lowest SBP was significantly higher in the continued group (-46.06 vs. -19.59; p=0.013). Both groups had a mean length of stay of approximately seven days.

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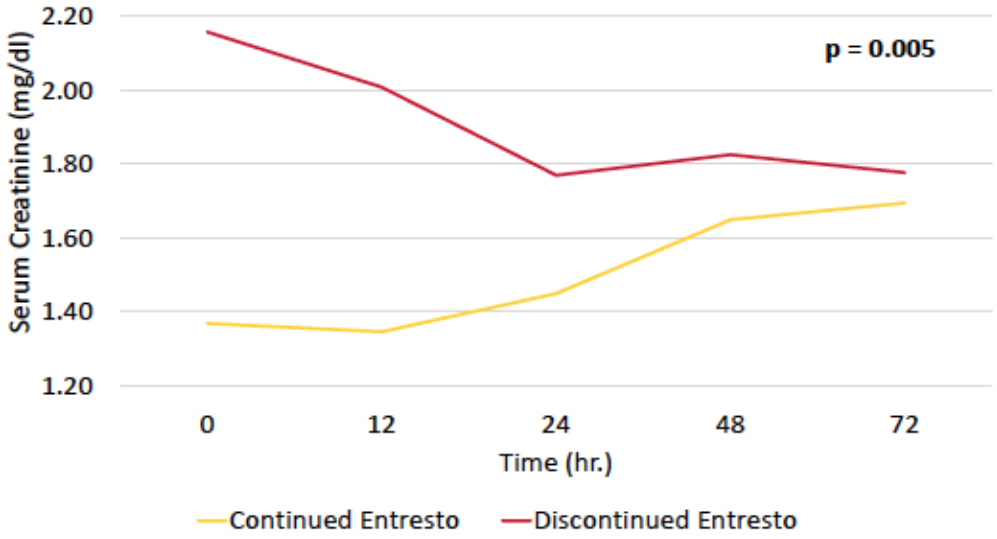
Table 1. Primary and Secondary Outcomes

	Continued Group (n=17)	Discontinued Group (n=7)	*P* value
Primary Outcomes			
% change in SCr, mean ± SD	-2.95 ± 25.2	-39.82 ± 18.4	0.0019
Occurrence of ≥1 hypotensive episode, No. (%)	17 (100.0)	6 (85.7)	0.1114
Secondary Outcomes (mean ± SD)			
% weight change at discharge	-3.27 ± 4.7	-5.81 ± 3.8	0.2154
% CrCl change at discharge	-4.66 ± 19.2	22.99 ± 11.0	0.0005
% change to lowest SBP	-46.06 ± 17.8	-19.59 ± 18.7	0.013
No. of hypotensive occurrences	10.06 ± 12.7	14.00 ± 15.1	0.5836
Time to first hypotensive episode (hr)	22.18 ± 16.0	16.17 ± 15.4	0.4709
Length of hospitalization (days)	7.00 ± 8.0	7.28 ± 3.2	0.9064

SCr, serum creatinine; CrCl, creatinine clearance; SBP, systolic blood pressure

Figure 1. Change in SCr (72 hrs.)



Conclusion: Based on our results, the patients who had sacubitril/valsartan discontinued on admission appeared to have higher degree of critical illness with higher incidence of severe heart failure symptoms, hypotension, AKI, and inotrope use, thus warranting discontinuation of sacubitril/valsartan upon admission. The discontinued group demonstrated increased rates of hypotensive occurrences throughout admission possibly due to increased severity of illness. Patients in the discontinued group demonstrated a greater serum creatinine recovery than the continued group. These results suggest that discontinuation of sacubitril/valsartan may be warranted among patients with ADHF if they present with signs of end-organ damage (e.g., AKI, hypotension, cardiogenic shock) to avoid further decompensation.

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Patient Perspectives on Barriers to Medication Adherence and Drug Utilization Post-Discharge

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Purpose: Medication adherence and drug utilization post-discharge are essential components that determine the quality of care in recently-hospitalized patients. Compared to the inpatient setting, monitoring of patient status and progress following discharge can be uneven or suboptimal. The primary goal of care is to ensure patient safety and access to appropriate treatments, regardless of the care setting. To attain patient safety goals post-discharge, it will be important to understand the barriers to medication adherence and optimal drug utilization. This study presents qualitative data on patient experiences with post-discharge pharmaceutical drug management and presents patients' suggestions for overcoming barriers to medication adherence.

Methods: We conducted focus groups and one-on-one in-depth interviews with adult post-discharge patients (n = 37) in order to explore their perspectives on the effectiveness and practicality of discharge plans. Eligibility criteria included adult patients aged 18 years+ discharged directly home within one year from the medicine service unit of two Maryland hospitals (one urban, one suburban). Focus groups and one-on-one interviews were audio-recorded and transcribed. Two members of the research team coded transcripts to consensus. Content analysis followed established qualitative methods of deductive coding—searching for themes guided by the project objectives and aims—and inductive coding—creating new domains based on new, often unexpected themes that organically developed. Key themes included factors associated with post-discharge care; quality and importance of patient-provider communication across the hospitalization continuum; reasons for hospital readmission; and suggestions for improving quality of transition from inpatient to home care. The current study presents the data on patients' experiences with pharmaceutical drug management post-discharge.

Results: Patients identified medication adherence as one of their top goals post-discharge. Barriers to optimal medication adherence included prohibitive co-payments, unexpected side effects, and contradictory recommendations from providers. Facilitators to adherence included detailed written information about drug regimens; communication between hospital physicians and outpatient or primary care providers; and assistance from non-medical hospital staff (e.g., social workers). In addition, health literacy was integral to optimal drug utilization, as patients who were adept at keeping track of medication-related details (e.g., dosages, side effects, and intended uses) or who had caregivers seek answers to their medication concerns prior to hospital discharge, reported being able to follow through with prescribed regimens. Patients' recommendations for decreasing non-adherence and adverse event-related readmissions included improving provider-to-provider communication, addressing financial and transportation barriers to prescription purchasing, and using "down time" during hospital stays to educate patients on their post-discharge medication plan.

Conclusion: Patients identified barriers to medication adherence and optimal drug utilization post-discharge. From the patients' perspectives, higher quality post-discharge care to support their health goals would be achieved by improved care coordination, patient-provider communication, and education during the inpatient stay.

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Comparison of Metoprolol and Diltiazem for Acute Management of Atrial Fibrillation in Patients with Heart Failure with Reduced Ejection Fraction

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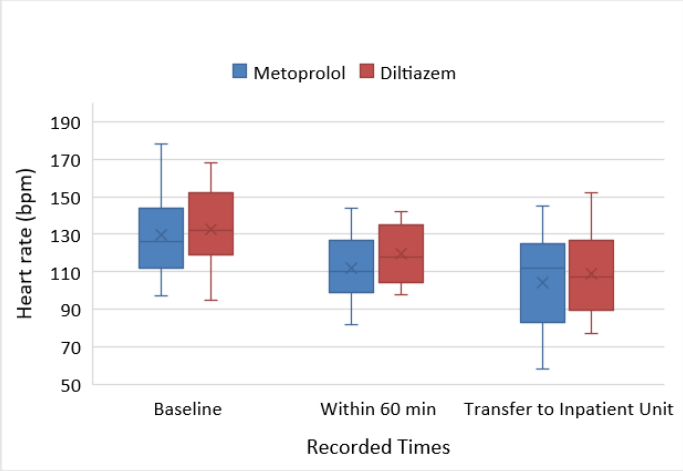
Purpose: Beta blockers (BB) and nondihydropyridine calcium-channel blockers (CCBs) are recommended to manage acute atrial fibrillation (AF). However, providers have often been advised to avoid nondihydropyridine CCBs in patients who have coexisting heart failure with reduced ejection fraction (HFrEF) due to the negative inotropic effects which can lead to increased risk of mortality with long-term use. This study aims to compare the safety and effectiveness of metoprolol (BB) and diltiazem (CCB) in the acute treatment of AF with rapid ventricular response (RVR) and concurrent HFrEF.

Methods: This was a single-center, retrospective cohort study approved by the local Institutional Review Board. Patient data was collected from the Emergency Department (ED) records from November 1st, 2015 to June 30th, 2018. Patients 18 years of age or older were included if they had a diagnosis of AF with RVR (defined as heart rate (HR) $\geq$ 120 beats per minute (bpm)) and HFrEF (EF $\leq$ 40%), had been treated with intravenous (IV) metoprolol or diltiazem, and admitted to ED during the study period. Patients were excluded if any of the conditions were met: EF > 40%, current pregnancy, history of allergic reaction to diltiazem and metoprolol, occurrence of crossover in treatment medications, pre-treatment systolic blood pressure (SBP) < 90 mmHg, or presence of acute decompensated heart failure (ADHF). A total of 290 patients were screened and 24 patients were included based on these criteria. The primary outcome was successful HR control within 60 minutes of drug administration (defined as HR < 100 bpm or HR reduction $\geq$ 20%). Secondary outcomes included successful HR control during transfer to inpatient unit, maximum median change in HR, bradycardia (HR < 60 bpm), hypotension (BP < 90/60 mmHg), median length of hospitalization, and readmission within 7 days.

Results: Of the 24 patients included, 15 patients received metoprolol and 9 patients received diltiazem. Primary outcome of successful HR control within 60 minutes occurred in 20% of patients who received metoprolol and 33.3% of patients who received diltiazem (p=0.81) but was not statistically significant (Figure 1). Successful HR control during transfer to inpatient unit was achieved in 40% of the metoprolol group and 66.7% of the diltiazem group (p=0.21). The maximum median change in HR was 32.5 [5 - 59] for metoprolol and 45 [14 - 71] for diltiazem (p=0.17). No significant difference was found between the two groups in rates of adverse events such as bradycardia and hypotension (p=0.15 and p=0.25, respectively). The median length of hospitalization was 6 [2 - 18] days for the metoprolol group and 4 [1 - 21] days for the diltiazem group. None of the patients given diltiazem were readmitted within 7 days, whereas 13.4% of patients given metoprolol were readmitted.

Figure 1: Heart Rate Measured at Baseline, Within 60 Minutes, and at Transfer to Inpatient Unit



Conclusion: There was no statistical difference in successful HR control within 60 minutes among patients who received IV metoprolol or IV diltiazem. There was also no statistical difference among the listed secondary outcomes. Despite the lack of significant difference and study limitations, patients given diltiazem had a larger maximum median change in HR, less rates of adverse events, shorter length of hospitalization, and no readmission within 7 day. Current literature highlights the risks associated with long-term use of nondihydropyridine CCBs. However, as this study presented, IV diltiazem showed comparable effectiveness and safety as IV metoprolol in an acute setting, and further research is warranted to support this data.