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Initiation of Disease-Modifying Antirheumatic Drugs in Older Medicare Beneficiaries With New Diagnosis of Late-Onset Rheumatoid Arthritis

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Objective. Older adults with rheumatoid arthritis (RA) account for up to one-third of the RA population and are less likely to receive optimal treatment. For the subgroup of older adults with late-onset RA (LORA), who experience more symptomatic and progressive disease, suboptimal treatment could be more consequential than the general population who age with RA. We evaluated use of disease-modifying antirheumatic drugs (DMARDs) in older adults with a new diagnosis of LORA.

Methods. In this retrospective observational study, we identified adults 66 years of age or older with a new diagnosis of LORA using Medicare data from 2008 to 2017. Information on baseline patient characteristics and DMARD initiation during the first 12 months after LORA diagnosis were collected. We also assessed concomitant use of glucocorticoids (GCs).

Results. We identified 33,373 older adults with new diagnosis of LORA. Average age at LORA diagnosis was 76.7 (SD 7.6); 75.4% were female, 76.9% were White, and 35.6% had low-income subsidy (LIS). Less than one-third were initiated on a DMARD (28.9%). In multivariable analyses, DMARD initiation was associated with younger age, fewer comorbidities, and absence of LIS status. Concomitant long-term (>3 months) GC use was higher among those on any DMARD (44.3%) compared with those without (15.2%).

Conclusions. DMARD initiation after new diagnosis of LORA is low despite current clinical practice guidelines recommending early aggressive initiation of treatment. Long-term GC use is common among those on any DMARDs, raising concern for suboptimal DMARD use. Further studies are needed to understand drivers of DMARD use in older adults.

INTRODUCTION

Improved quality of care and increased life expectancy have led to a rapidly growing population of older adults living with chronic, debilitating, and costly rheumatoid arthritis (RA).[1–3] RA disproportionally affects older adults as the incidence of RA continues to increase until the ages of 75 to 80 years, whereby almost one-third of patients with RA are older than 60 years of age.[4] Moreover, older adults with RA can be classified into two clinically distinct subgroups with differing characteristics and prognosis based on age of RA onset. Individuals diagnosed with RA after 65 years of age have late-onset RA (LORA), which is characterized by more equal gender distribution, higher frequency of acute presentation with systemic features, higher disease activity, more radiographic progression, and greater functional decline.[4–7]

In recent years, the treatment paradigm of RA has evolved from traditional step-up to more aggressive treat-to-target (T2T) strategies that promote early initiation, escalation, and combined use of conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) and biologic DMARDs (bDMARDs).[8] Although DMARDs improve clinical, functional, and radiographic outcomes in patients with RA, older adults are less likely to receive

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treatment.[9–11] In a single-state study of Medicaid and Medicare beneficiaries, only 15% to 30% of older adults received DMARDs, and older adults 75 years of age and older were two to three times less likely to receive DMARDs compared with those between the ages of 65 and 74.[11] This is in contrast to prior studies showing that on average, 30% to 44% of all patients with RA in nonspecialized ambulatory settings and more than 70% of those followed by rheumatologists receive DMARDs.[12]

Although data are scarce and inconsistent, the few studies investigating efficacy of DMARDs have not revealed decreased effectiveness of csDMARDs or bDMARDs in older adults.[13,14] Although overall rates of adverse effects associated with DMARD use were comparable with that in younger adults, the use of bDMARDs was associated with two to three fold increase in risk of serious infectious complications for older adults 65 years of age or older.[13,15] In addition to DMARDs, glucocorticoids (GCs), alone or in combination with DMARDs, are commonly used to relieve symptoms of RA.[11,16] However, current clinical practice guidelines recommend limiting the use of GCs because of their adverse effects profile, including the risk of serious infections even with low doses.[17] Therefore, especially if able to reduce long-term GC use, older adults with LORA may achieve improved quality of life, better outcomes, and less disability with more aggressive treatment with DMARDs, provided they are appropriately screened and monitored for associated risks. To our knowledge, treatment of LORA in usual care among a contemporary cohort of older adults is unknown.

In this study, we evaluated initiation of DMARDs in older adults with new diagnosis of LORA using nationally representative Medicare claims data. We also examined use of long-term (>3 months) GCs after LORA diagnosis and the impact of long-term GC use or serious infection requiring hospitalization prior to LORA diagnosis on DMARD initiation.

PATIENTS AND METHODS

We used 20% Medicare data between 2008 and 2017 from the Master Beneficiary Summary File, Medicare Provider Analysis and Review, Outpatient, Carrier, and Part D Event files. Medicare data were used for this study because older adults are often excluded from clinical trials[18,19] and observational studies using large, nationally representative administrative data allow for understanding treatment in usual care. This study was deemed exempt by the institution review board at the University of Michigan (HUM00186525).

Study population and variables. We adopted a previously validated claims-based algorithm for RA, which has a positive predictive value of 76% to 81%,[10,20] to select an inception cohort of older adults with new diagnosis of LORA and enrollment in continuous fee-for-service Medicare.

We identified Medicare beneficiaries who met criteria for RA based on two or more outpatient visits with International Classification of Diseases (ICD) codes for RA diagnosis at least 7 days apart but within 365 days. To be considered newly diagnosed with LORA, a minimum baseline period of 12 months without diagnosis code for RA or associated prescription for DMARD claims was required. Index date was defined as the earliest date that a patient fulfilled criteria for LORA. We further limited the cohort to those who had continuous fee-for-service, including Part D enrollment, during the 12 consecutive months preceding and after the index date. Therefore, the study cohort consisted of Medicare beneficiaries who met criteria for new diagnosis of LORA between January 1, 2009, and December 31, 2016, and were 66 years of age or older on the index date. Participants were censored at death or end of the study period.

The independent variables were patient characteristics, including age at time of LORA diagnosis, sex, race and ethnicity, and low-income subsidy (LIS) status. Comorbidity was calculated using the Elixhauser Comorbidity Index (ECI), which has been adapted for use with ICD codes in administrative data, and has been validated to be predictive of in hospital mortality, length of hospital stay, functional decline, and health care use.[21] To account for differences in ICD-9 and ICD-10 versions of the ECI, disease conditions, excluding autoimmune conditions, were grouped into 25 clinically similar categories to calculate summative ECI scores. Beneficiaries were categorized into three groups based on having less than 3, 3 to 5, and 6 or more comorbid conditions. Serious infection requiring hospitalization at baseline was identified using ICD-based algorithm adapted from the literature for any infection involving the respiratory tract, skin and soft tissue, genitourinary tract, gastrointestinal tract, central nervous system, and septicemia/sepsis in any position of the discharge diagnosis from inpatient files during the 12 months prior to LORA diagnosis.[22,23]

Treatment of LORA (DMARD and GC use). Current RA clinical practice guidelines recommend the initiation of DMARDs, categorized as csDMARDs or bDMARDs, either alone or in combination, within three months of RA onset.[8] We evaluated initiation of DMARDs during the first 12-months post-index date of LORA diagnosis based on having any (ie, one or more) prescriptions for DMARDs. We categorized patterns of DMARD initiation as early (<90 days) versus late (≥90 days) initiation and either as csDMARD only, bDMARD only, or combined use of csDMARDs and bDMARDs.

We used the IBM Redbook to identify prescription claims for DMARDs and oral GCs based on National Drug codes from Part D event files. Five csDMARDs (methotrexate, sulfasalazine, hydroxychloroquine, leflunomide, and azathioprine) and 8 bDMARDs (adalimumab, etanercept, infliximab, certolizumab, golimumab, abatacept, tofacitinib, and tocilizumab) were identified. We did not include evaluation of bDMARDs approved after 2015, namely baricitinib and sarilumab, as we used Medicare claims data from 2008 to 2016. We also excluded evaluation of rituximab and its biosimilars as these medications are not usually

recommended as first-line bDMARD for new diagnosis of RA and have prolonged dosing intervals (eg, every 6 months).

Detailed information on prescription quantity and duration was collected to identify those with long-term GC use, defined as having near daily prescriptions for GCs for more than 3 months during a 12-month period. GC monotherapy was further defined as GC use for more than six months without any DMARD use.

Statistical analyses. We used descriptive statistics to characterize the cohort and compare older adults who were initiated on DMARDs to those without any DMARD use during the first 12 months after a new diagnosis of LORA. We used multivariable logistic regression models, adjusting for patient age at index date, sex, race and ethnicity, LIS status, comorbidity status, and year of LORA diagnosis to evaluate patient characteristics associated with DMARD initiation. In additional series of multivariable models, we examined the association between DMARD initiation and long-term GC use or serious infection requiring hospitalization during the 12 months prior to LORA diagnosis, adjusting for patient characteristics and year of LORA diagnosis.

Data were analyzed using SAS Enterprise Guide 8.1 (SAS Institute Inc.). A *P* value less than or equal to 0.05 is considered statistically significant.

RESULTS

We identified 33,373 older adults with new diagnosis of LORA in continuous fee-for-service Medicare, including Part D coverage. Average age at LORA diagnosis was 76.7 (SD 7.6) years; 75.4% were female, 76.9% were White, 35.6% had LIS, and 58.2% had three or more comorbid conditions (Table 1). During the 12 months prior to new diagnosis of LORA, 38.1% had at least one prescription for GCs and 9.8% had long-term GC use.

During the first 12 months after LORA diagnosis, less than one-third (28.9%) were initiated on some form of DMARD. The proportion of older adults initiated on DMARDs was stable between 2009 and 2015 and ranged between 26.7% and 30.8% (Figure 1). Among those on any DMARD treatment (N = 9640), 90.1% were initiated csDMARD only, 2.6% on bDMARD only, and 6.8% on both classes of DMARDs. Three in four were initiated on some form of DMARDs within 90 days of new LORA diagnosis (ie, early initiation). Concomitant long-term GC use after LORA diagnosis was common and observed in 44.3% of older adults with any DMARD use.

Among older adults who were not initiated on any DMARD treatment (N = 23,733), 15.2% were on long-term GCs and 10.8% were on GC monotherapy. Over the study period, among all older adults with LORA, the proportion on GC monotherapy alone without any DMARD ranged from 6.3% to 8.8%. (Figure 1). To evaluate whether those on GC monotherapy had other indications for GC use, we performed sensitivity analyses and found 168 (6.6%) to have steroid responsive pulmonary conditions (eg, asthma, chronic obstructive pulmonary disease).

In multivariable analyses that included patient characteristics and year of LORA diagnosis as covariates, DMARD initiation after LORA diagnosis was associated with younger age, fewer

Table 1. Characteristics of Medicare beneficiaries with new diagnosis of late-onset RA*

Characteristics	All LORA beneficiaries N = 33,373	No DMARD initiation n = 23,733	Any DMARD initiation n = 9640	*P* value
Sociodemographic				
Age at diagnosis, mean (SD)	76.7 (7.6)	77.6 (7.9)	74.4 (6.3)	<0.0001
Female, n (%)	25,160 (75.4)	18,079 (76.2)	7,081 (73.4)	<0.0001
Race, n (%)				<0.0001
White	25,652 (76.9)	17,957 (75.6)	7,695 (79.8)	
Black	3,424 (10.3)	2,606 (11.0)	818 (8.5)	
Hispanic	2,838 (8.5)	2,144 (9.0)	694 (7.2)	
Other	1,459 (4.4)	1,026 (4.3)	433 (4.5)	
Low-income subsidy, n (%)	11,893 (35.6)	9,420 (39.7)	2,473 (25.5)	<0.0001
Comorbidity, n (%)				<0.0001
<3	13,941 (41.8)	9,082 (38.3)	4,859 (50.4)	
3-5	13,964 (41.8)	10,196 (43.0)	3,768 (39.1)	
≥6	5,468 (16.4)	445 (18.8)	1,013 (10.5)	
Year of LORA diagnosis, n (%)				<0.0001
2009	4,324 (13.0)	3,170 (13.4)	1,154 (12.0)	
2010	3,784 (11.3)	2,729 (11.5)	1,055 (11.0)	
2011	3,597 (10.8)	2,582 (10.9)	1,015 (10.5)	
2012	3,499 (10.5)	2,483 (10.5)	1,016 (10.5)	
2013	3,318 (9.9)	2,348 (9.9)	970 (10.1)	
2014	3,658 (11.0)	2,532 (10.7)	1,126 (11.7)	
2015	5,066 (15.2)	3,665 (15.4)	1,401 (14.5)	
2016	6,127 (18.4)	4,224 (17.8)	1,908 (19.7)	

*DMARD = disease-modifying antirheumatic drug; LORA = late-onset rheumatoid arthritis; RA = rheumatoid arthritis.

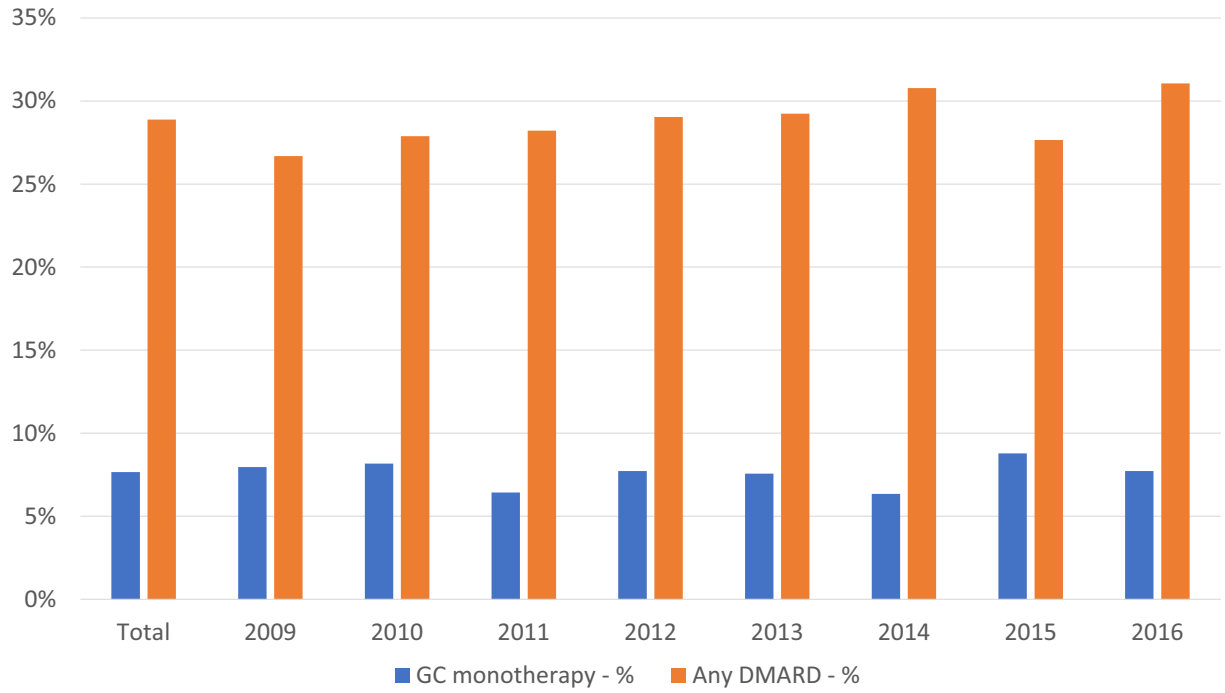

Figure 1. DMARD = disease modifying anti-rheumatic drugs, GC = glucocorticoids, GC monotherapy = GC use only for >180 days without any DMARD use. Proportion of older adults with DMARD initiation or glucocorticoid monotherapy (without any DMARDs) after new diagnosis of late-onset RA

comorbidities, and absence of LIS status, adjusting for sex and race and ethnicity (Table 2). In additional series of models, long-term GC use (odds ratio [OR] 0.91, 95% confidence interval [95% CI] 0.84–0.99) was associated with lower odds of DMARD initiation; and likewise, serious infection (OR 0.81, 95% CI 0.73–0.90) was also associated with lower odds of DMARD initiation, both adjusting for patient characteristics of age, sex, race and ethnicity, comorbidity, LIS status, and year of LORA diagnosis. In sensitivity analysis examining the effect of both clinical conditions in the same model, only serious infection (OR 0.82, 95% CI 0.74–0.91) and not long-term GC use (OR 0.92, 95% CI 0.85–1.00) prior to LORA diagnosis was significantly associated with DMARD initiation.

DISCUSSION

In this study, DMARD initiation in older adults with a new diagnosis of LORA was low (28.9%) and associated with younger age, fewer comorbidities, and absence of LIS status. Moreover, DMARD initiation was less likely in those with long-term GC use or serious infection requiring hospitalization prior to LORA diagnosis, adjusting for patient characteristic. Long-term use of GCs after LORA diagnosis was common and more prevalent among those on any DMARD (44.3%) compared with those without DMARD use (15.2%). Among those not on any DMARDs, 10.8% were on GCs alone for more than six months (ie, monotherapy) during the first year after LORA diagnosis.

As the population is aging globally, the number of older adults living with RA, and by extension with LORA, is growing. However, we lack guidelines specific to older adults with rheumatic disease, as they are often excluded from randomized clinical trials for reasons of multimorbidity and polypharmacy common in this population.[24] This leaves a gap in our knowledge of the optimal use of DMARDs for medically complex older adults, where the drugs may be beneficial but pose some risks. In the absence of trial data, observational studies serve an important role in filling this type of scientific knowledge gap and also allow for understanding drivers of treatment choices and outcomes in usual care. In a Canadian registry based study from 2008 to 2020, patients with LORA (n = 354) were compared with those with younger onset RA (n = 518) and were found to have similar prognosis in terms of time to remission, adjusting for other prognostic factors, including multimorbidity and GC use.[25] At remission, patients with LORA were more likely to be on a single csDMARD. In a Swedish RA registry based study (n = 950) from 1995 to 2011, patients with LORA were treated later and less often with DMARDs and treated more often with GCs.[26] As the most aging nation in the world, Japan has a number of studies on the LORA population and one prospective study evaluated the safety and efficacy of following a T2T strategy to target low disease activity over a three year period.[27] Of the 197 patients

Table 2. Patient characteristics associated with initiation of any DMARD after new diagnosis of late-onset RA among Medicare beneficiaries 66 years of age or older*

Variables	OR (95% CI)	
	Unadjusted	Adjusted
Age at LORA diagnosis[a]	0.94 (0.94–0.95)	0.95 (0.94–0.95) †
Female	0.87 (0.82–0.91)	0.99 (0.94–1.05)
Race		
White (ref)	1	1
Black	0.73 (0.67 0.80)	0.94 (0.86–1.03)
Hispanic	0.76 (0.69–0.83)	1.01 (0.92–1.11)
Other	0.99 (0.88–1.11)	1.12 (0.99–1.27)
Low-income subsidy[a]	0.52 (0.5–0.55)	0.57 (0.54–0.60) †
Comorbidity		
<3 (ref)	1	1
3-5†	0.69 (0.66–0.73)	0.81 (0.77–0.85) †
≥6[a]	0.43 (0.39–0.46)	0.54 (0.50–0.59) †
Year of LORA diagnosis		
2009 (ref)	1	1
2010	1.06 (0.96–1.17)	1.09 (0.99–1.21)
2011	1.08 (0.98–1.19)	1.1 (0.99–1.22)
2012	1.12 (1.02–1.24)	1.14 (1.03–1.26)
2013	1.14 (1.03–1.26)	1.11 (1.00–1.23)
2014	1.22 (1.11–1.35)	1.14 (1.03–1.26)
2015	1.05 (0.96–1.15)	0.94 (0.86–1.04)
2016	1.24 (1.14–1.35)	1.04 (0.95–1.14)

*CI = confidence interval; DMARD = disease-modifying antirheumatic drug; OR = odds ratio; RA = rheumatoid arthritis.
[a]Statistically significant (adjusted model) with $P < 0.05$.

with LORA, 65% adhered to T2T, and among them 58% and 70% achieved remission by the Simplified Disease Activity Index (SDAI) and Health Assesment Questionnaire Disability index (HAQ-DI), respectively. This is in contrast to the remission rate of 35% by SDAI and 43% by HAQ-DI among the patients with LORA who did not adhere to T2T. These studies show that DMARDs are generally well tolerated, and remission is possible in older adults with LORA, and yet, DMARD use is low in this population. In this study, younger age was associated with increased odds of DMARD initiation, which aligns with prior observations that older adults receive less aggressive treatment and age influence rheumatologists' treatment recommendations.[9,10,28–30] Additionally, those with a history of serious infection or long-term GC use were less likely receive any DMARD, including csDMARDs, despite their relative safety and benefit. A study using Medicare data showed that rheumatologists who care for more beneficiaries 75 years of age or older are more likely to prescribe bDMARDs for older adults.[31] This suggests that experience with and familiarity caring for older adults may influence physician prescribing behaviors and that targeted education and interventions may improve DMARD use in older adults with LORA.

In addition to age and comorbidity, absence of LIS status was associated with increased odds of DMARD initiation. The LIS is a Medicare program designed to lower the costs of Medicare prescription drug coverage for beneficiaries with limited income and resources.[32] Studies have shown those with low socioeconomic status (SES) experience more obstacles to health care access, experience more delays in treatment, and are less likely to adhere to treatment because of lower-trust in the health care system and medication cost-related barriers.[33,34] Along with SES, racial and ethnic differences in medication use and preferences for treatment of RA have been observed.[35] However, race and ethnicity was not significantly associated with DMARD initiation in older adults with LORA in this study. Health disparity is complex and arises from the interrelation of multiple factors, including race and ethnicity, SES status, education level, disability status, culture, health care access, health behaviors, and age. Dissecting the overlapping aspects or contribution of these factors to explain disparities warrant further investigation.

This study has limitations common to claims-based observational analyses. Although we use individual-level identifiable data that contains details of treatments, diagnoses, and dates, the ascertainment of RA and comorbidity diagnoses relies on the completeness and accuracy of administrative bills recorded by physicians. Information on seropositivity and disease activity are not available through claims data and some measures, such as functional status, can only be measured by use of proxies, such as wheelchair use. The duration of DMARD use or GC doses were not evaluated as we were interested in any exposure to these medications. In addition, although the use of prescription fill records to study patterns of prescription drug use have been validated, it does not measure adherence or actual use of medication or use of over-the-counter medications. Increasingly, more external datasets are being linked to Medicare data to connect the strengths and features of different datasets. Future studies using Medicare-linked datasets will allow incorporation of clinically relevant information to enhance our understanding of treatment in older adults. We are not using the newly available Medicare Advantage data because methods have not yet been validated in those data. As a result, findings from this study may not be generalized to the managed care population.

In conclusion, less than one-third of older adults with new diagnosis of LORA receive the standard of care despite DMARD use being a quality measure for RA management and clinical practice guidelines recommending early aggressive initiation of treatment. Moreover, among those not on any DMARDs, one in 10 older adults with LORA are on GC monotherapy that are symptom relieving but not disease modifying and associated with an adverse risk profile. GC monotherapy for more than 180 days indicate this group of older adults with LORA likely have established a diagnosis of LORA and are likely to respond to some form of steroid-sparing treatment, thus raising concerns for suboptimal DMARD use in this population. Further research is needed to explore drivers of suboptimal DMARD use, subpopulations at risk of poor outcomes, and patient-and provider-identified facilitators and barriers to DMARD use. With growing evidence for use of DMARDs among older adults and new information on factors that drive prescribing in the aging population, interventions could be designed to optimize treatment of older adults with RA.

AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published. Dr. Lee had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. Lee, Martindale, Makris, Yung, Bynum.
Acquisition of data. Lee, Martindale.
Analysis and interpretation of data. Lee, Martindale, Makris, Yung, Bynum.

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