OM1

Findings From A Real-World Cohort

Rheumatology, Cardiovascular

Scientific Findings

RHEUMATOLOGY

CARDIOVASCULAR

**Findings are from a large contemporaneous real world cohort*

1. Comparison of Improvements in Disease Activity between Classes of Biologic Disease Modifying Anti-Rheumatic Drugs in Routine Clinical Practice: Findings from a Large Contemporaneous Real World Cohort

Zhaohui Su, Gregory Donadio, Tom Brecht, Costas Boussios, Francis O'Donovan, Charles Kekeh, Anna Lafontant, Kathryn Starzyk, Richard Gliklich, Vandana Menon; *ACR/ARHP Annual Meeting. November 4-8, 2017. San Diego, CA.*

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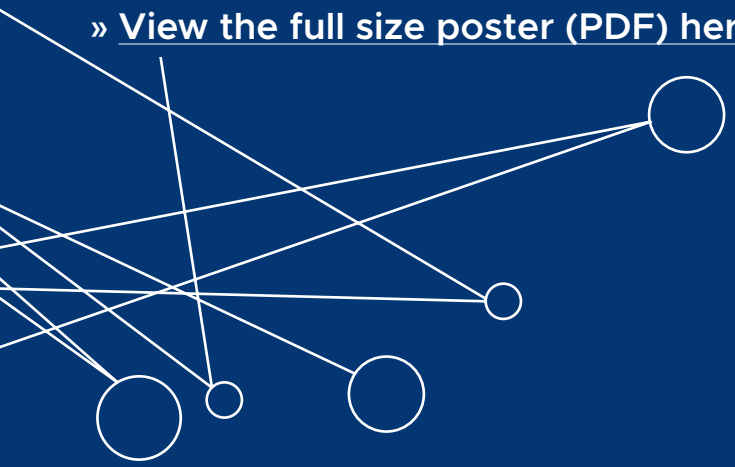


Background

RA is estimated to affect approximately 1.3 million adults in the US and accounts for a significant proportion of US health care spending with direct medical costs of over $70 billion a year. The primary driver of cost in RA is the specialty drug classes. Given the cost differential between available RA treatments, it is critical to ensure that patients are receiving optimal therapy at the optimal time. We compared improvements in disease activity between biologic DMARD classes, in a large cohort of patients with RA, under conditions of routine clinical practice.

Methods

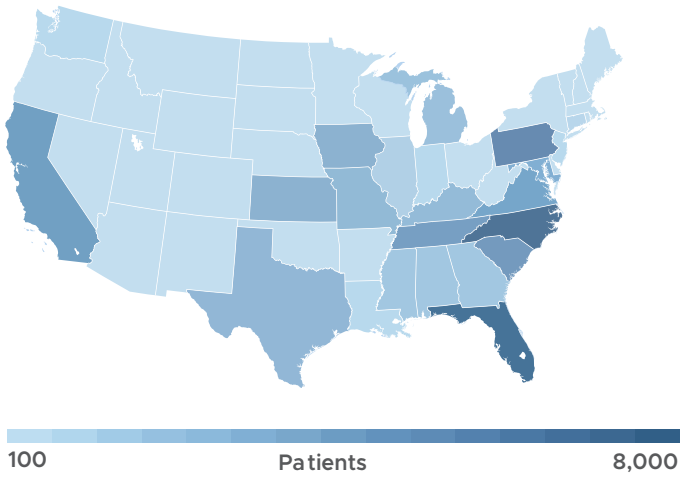
95,000+
Patients treated by rheumatologists

59,326
Patients had Disease Activity (DA) measures

3
Median number of DA measures per patient per year

The OM1 platform collects, links, and leverages structured and unstructured data from electronic medical records (EMR) and other sources in an ongoing and continuously updating manner. The OM1 RA Cohort includes nationally representative data on >95,000 patients treated by rheumatologists [**Figure 1**]. Disease activity measures (both measured and identified using advanced natural language processing) were available in 59,326 patients and established American College of Rheumatology cutpoints were used to define disease severity. There were a median of 3 disease activity measures per patient per year. The analysis included patients who were treated with the same biologic disease modifying anti-rheumatic drug (bDMARD) for a 6 month period and had disease activity measures at baseline and at 6 months.

Figure 1. Representative Geographic Distribution



Results

60
Mean age in years

76%
Female

71%
Caucasian

The mean±SD age was 60±14 years [**Figure 2**], 76% of the cohort was female, and 71% Caucasian. At baseline, 23% of patients were in remission, and 36%, 24% and 17% had low, moderate and high disease activity, respectively [**Figure 3**]. Total and swollen joint counts were available in ~40% of the cohort and erythrocyte sedimentation rate was available in 70%.

Figure 2. Representative Age Distribution

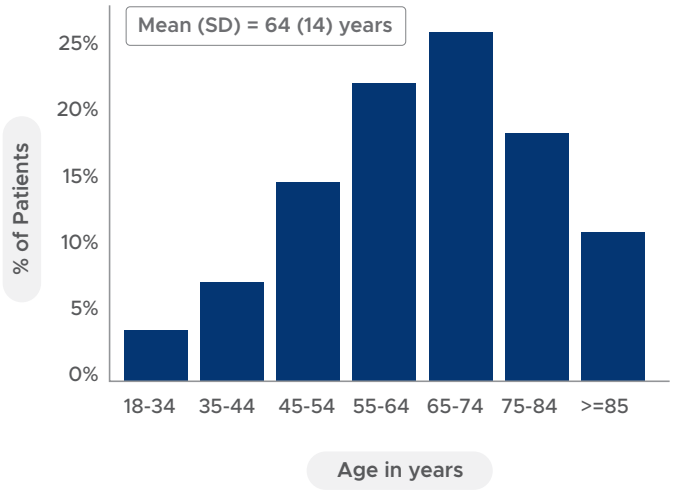
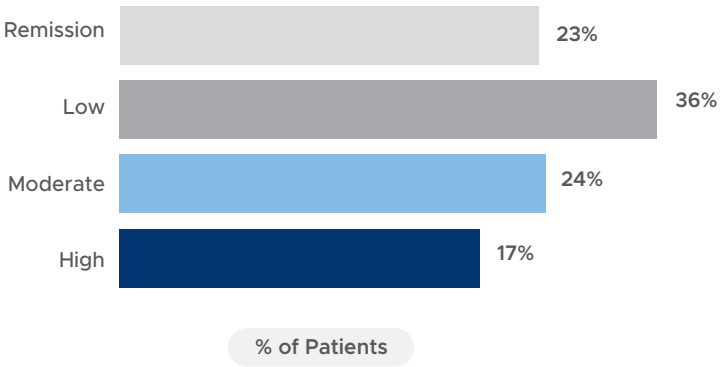


Figure 3. Disease Activity at Baseline (Entry to the OM1 RA Condition Cohort)



Results (continued)

At least one extra-articular manifestation was documented in 36% of patients [**Figure 4**].

During the study period, 44% of the cohort received nonbiologic DMARD and 45% bDMARD; tumor necrosis factor inhibitor (TNF-inhibitor) accounted for 77% of bDMARD. **Figure 5** presents the proportion of patients treated with bDMARD with moderate to severe disease at baseline, who achieved low or remission status within the subsequent 6 months. Analysis was stratified by whether the patient had documented prior treatment with biologics.

Figure 4. Distribution of Extra-articular Manifestations

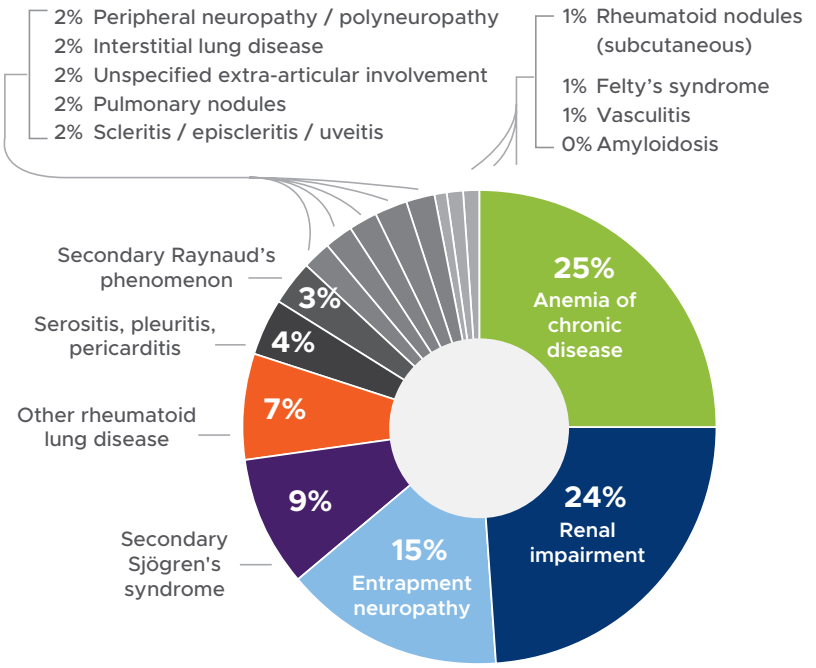
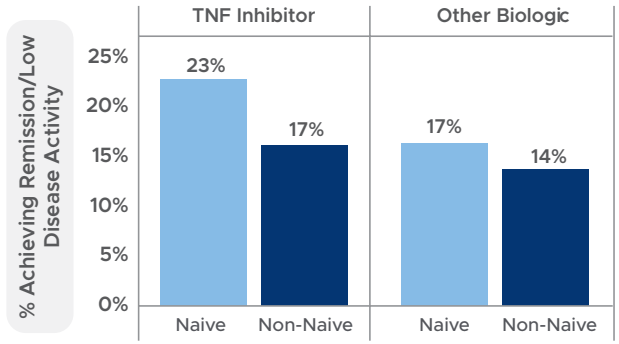


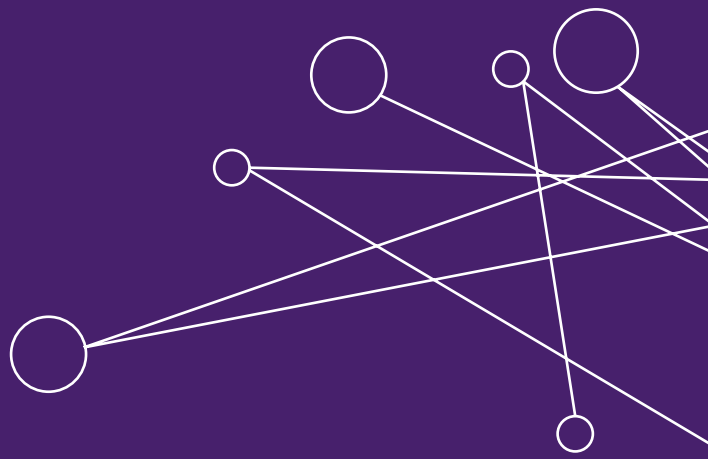
Figure 5. % of Patients Achieving Remission or Low Disease Activity Status after Failing the Previous Therapy, and Having Received 6 months of Treatment with Biologic DMARD



Conclusions

Using a data driven platform that enables large scale assessment (patient characteristics, treatment patterns, clinical outcomes) of patients, we found that naive patients treated with TNF-inhibitors showed the most improvement in disease activity overall. Among non-naive patients the TNF-inhibitor group had the highest proportion of patients achieving remission or low disease activity over a 6-month treatment period.

1. Comparison of Improvements in Disease Activity between Classes of Biologic Disease Modifying Anti-Rheumatic Drugs in Routine Clinical Practice



Naive patients treated with TNF-inhibitors showed the most improvement in disease activity overall.

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2. Initiation of Biologic Disease Modifying Anti-rheumatic Drug Therapy and Associated Changes in Disease Activity Measures in Routine Clinical Practice: Findings from a Large Contemporaneous Real World Cohort

Zhaohui Su, Tom Brecht, Anna Lafontant, Costas Boussios, Francis O'Donovan, Charles Kekeh, Kathryn Starzyk, Richard Gliklich, Vandana Menon; ACR/ARHP Annual Meeting. November 4-8, 2017. San Diego, CA.

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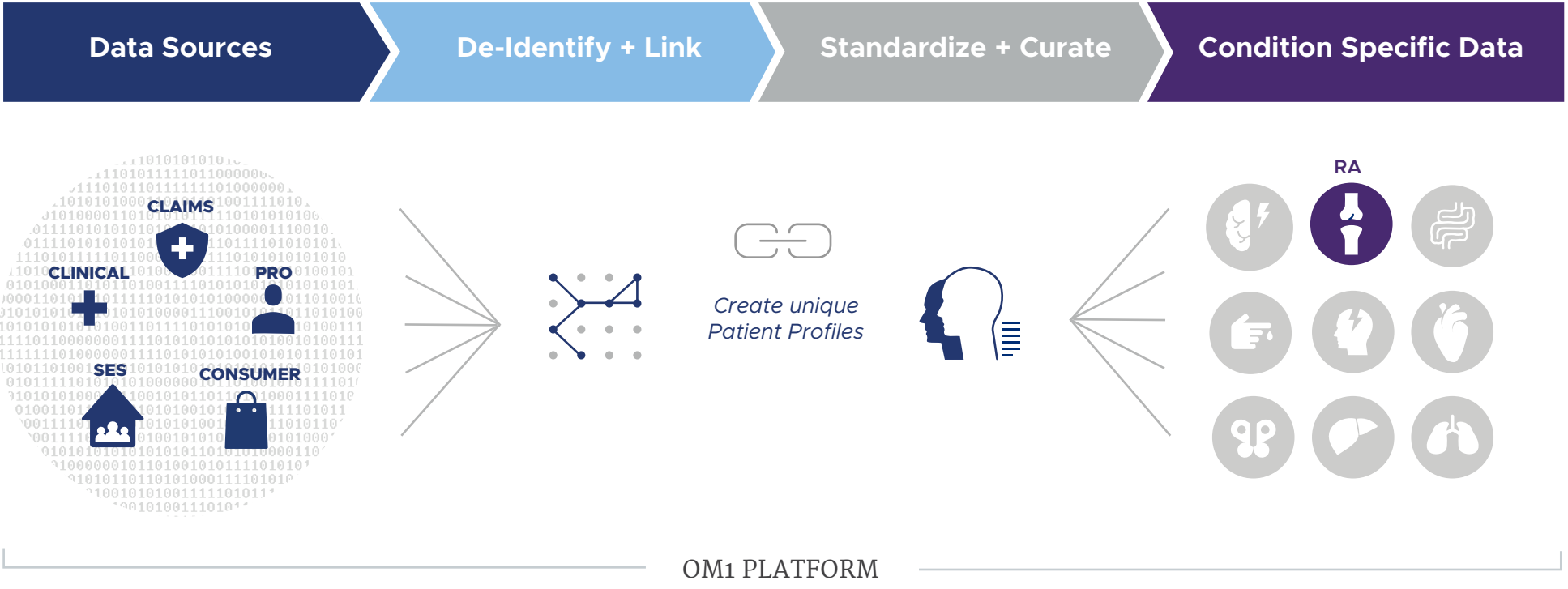
Background

While many clinical trials provide direct comparisons between biologic disease modifying antirheumatic drugs (bDMARD) and nonbiologic DMARD (nDMARD), there is a need for additional evidence on the effectiveness of these therapies in routine clinical practice. We evaluated changes in disease activity measures associated with bDMARD therapy, in a large cohort of patients with RA, under conditions of routine clinical practice.

Methods

The OM1 platform collects, links, and leverages structured and unstructured data from electronic medical records (EMR) and other sources in an ongoing and continuously updating manner.



Methods (continued)

95,000+
Patients treated by rheumatologists

RAPID-3, CDAI, DAS28
Disease Aciivity Measures used

Time to initial remission
Primary analysis

Time to confirmed remission
Secondary analysis

The OM1 RA Cohort includes data on >95,000 patients treated by rheumatologists. This analysis included patients who were treated with nDMARD between January 2013 and April 2017, had not received prior treatment with bDMARD, and either added or switched to another nDMARD or initiated bDMARD during the observation period (date of change in therapy is the index date). Established American College of Rheumatology cutpoints for standard disease activity measures (RAPID-3, CDAI, DAS28) were used to define remission, low, moderate and high disease activity categories. Advanced natural language processing was used to derive missing disease activity categories. Drug eras were defined using Observational Medical Outcomes Partnership (OMOP) definitions.

The primary analysis was time to initial remission, and a secondary analysis was time to confirmed remission defined as 2 consecutive scores denoting remission. To reduce the impact of subsequent treatment changes, data were censored at 12 months. To reduce the bias that more frequent disease activity measures may be associated with shorter time to remission, we matched the two groups on average number of disease activity measures per patient.

Methods (continued)

The following analyses were performed:

1. Intent-to-treat (ITT) analysis; non-biologic group includes patients who switched to biologic DMARDs within 6 months after the index date (**Figure 1**).

2. As-treated (AT) analysis; non-biologic group excludes patients who switched to biologic DMARDs within 6 months after the index date (**Figure 2**).

3. Subgroup analysis; the comparator group (nb-biologic shown in the figure) are patients who switched/ added non-biologic DMARDs but switched to biologic DMARDs within 6 months after the index date (**Figure 3**).

4. ITT analysis of time to confirmed remission; note if the last disease activity measure is remission and there are no future data available, this single remission outcome is considered as a remission in this analysis (**Figure 4**).

Results

The analysis cohort included 4,957 patients who met study inclusion criteria, none of whom were in remission at index date; 1,334 added or switched to another nDMARD and 3,623 added or switched to a bDMARD. There were an average of 4.2 disease activity measures per patient and a total of 20,605 disease activity measures during the 12 month study period. Age, gender, baseline disease activity measures, and Charlson Comorbidity Index, were similar in both groups [**Table 1**].

Table 1. Patient characteristics at the time of change in DMARD therapy (index date), stratified by DMARD class

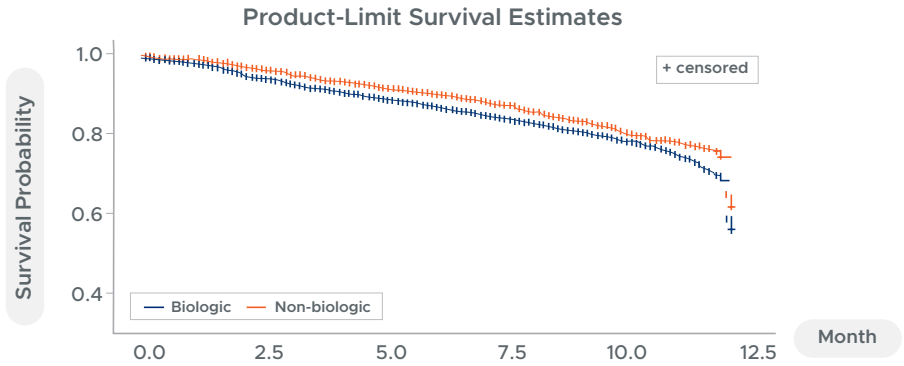
Characteristics		DMARD CLASS bDMARD N=3,623	DMARD CLASS nDMARD N=1,334	Total N=4,957
Female gender	n (%)	2,919 (81%)	1,110 (83%)	4,029 (81%)
Age (years) at index date	Mean (SD)	58 (13)	57 (13)	58 (13)
Charlson comorbidity index at index date	Mean (SD)	1.5 (1)	1.4 (1)	1.4 (1)
Baseline high disease activity	n (%)	1,530 (42%)	550 (41%)	2,080 (42%)
Number of disease activity measures	Mean (SD)	4.1 (2.5)	4.4 (2.6)	4.2 (2.5)
TJC at index date	Mean (SD)	5.775 (6.36)	5.15 (5.80)	5.644 (6.257)
Extra-articular manifestations	n (%)	882 (18%)	334 (7%)	1,216 (25%)

Results (continued)

In the primary ITT survival analysis, a larger proportion of patients in the bDMARD group achieved remission (p=0.013) within 12 months post the index date [**Figure 1**].

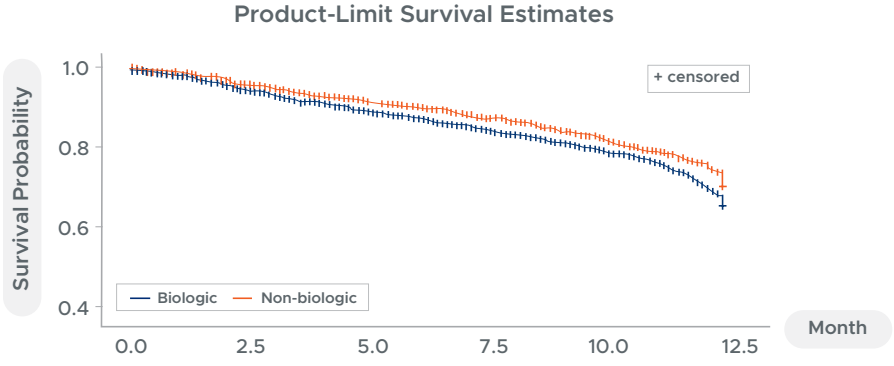
Time to remission was significantly shorter in the bDMARD group (mean±SD=5.2±3.4 months) compared to the nDMARD group (5.7±3.2 months, p<0.05). This finding is supported by the AT analysis (p=0.040) [**Figure 2**].

Figure 1. Initiating biologic DMARDs is associated with shorter time to remission in ITT analysis (Analysis #1; p=0.013)



Summary of the Number of Censored and Uncensored Values					
Stratum	Class	Total	Failed	Censored	% Censored
1	Biologic	3623	661	2962	81.76
2	Non-biologic	1334	219	1115	83.58
Total		4957	880	4077	82.25

Figure 2. Initiating biologic DMARDs is associated with shorter time to remission in AT analysis (Analysis #2; p=0.040)



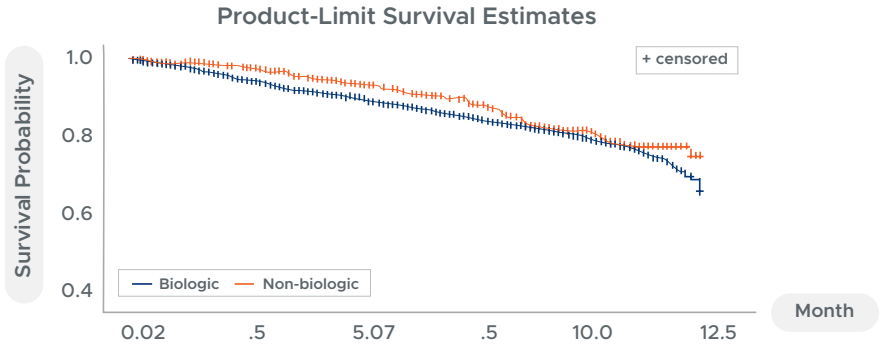
Summary of the Number of Censored and Uncensored Values					
Stratum	Class	Total	Failed	Censored	% Censored
1	Biologic	3623	661	2962	81.76
2	Non-biologic	834	142	692	82.97
Total		4457	803	3654	81.98

Results (continued)

In the subgroup analysis that compared patients who switched or added bDMARD immediately at the index date versus switching deferred by up to 6 months, the former group showed marginally significant shorter time to remission (p=0.095) [**Figure 3**].

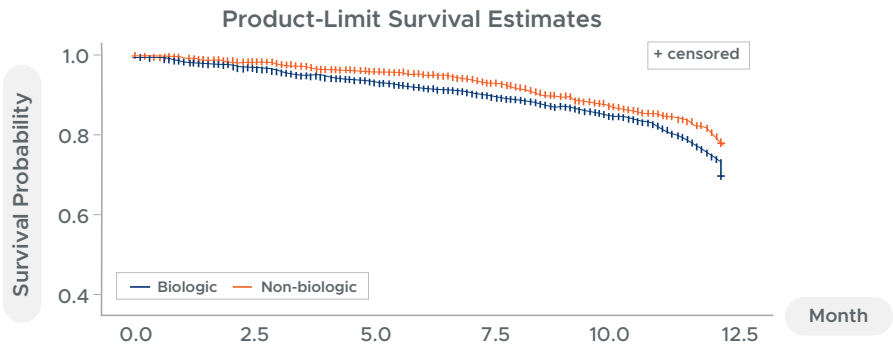
In the secondary ITT survival analysis, a larger proportion of patients in the bDMARD group achieved confirmed remission (p=0.003) compared to the nDMARD group [**Figure 4**].

Figure 3. Initiating biologic DMARDs is marginally associated with shorter time to remission in a subgroup analysis (Analysis #3; p=0.095)



Summary of the Number of Censored and Uncensored Values					
Stratum	Class	Total	Failed	Censored	% Censored
1	Biologic	3623	661	2962	81.76
2	Non-biologic	500	77	423	84.60
Total		4123	738	3385	82.10

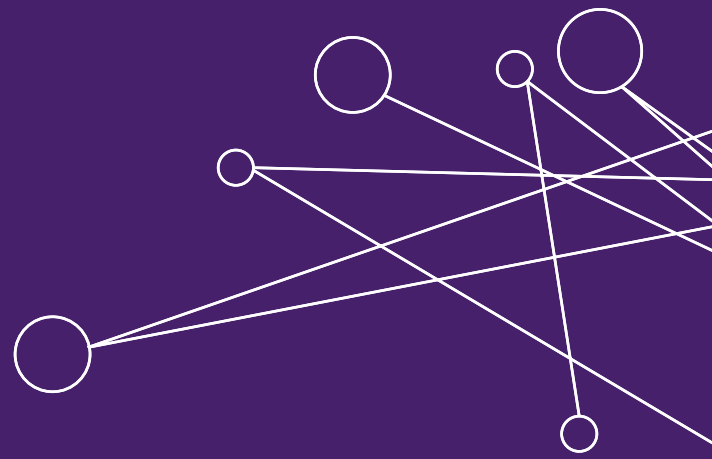
Figure 4. Initiating biologic DMARDs is associated with shorter time to sustained remission defined as the first of two consecutive remission disease activities (Analysis #4; p=0.003)



Summary of the Number of Censored and Uncensored Values					
Stratum	Class	Total	Failed	Censored	% Censored
1	Biologic	3623	486	3137	86.59
2	Non-biologic	1334	149	1185	88.83
Total		4957	635	4322	87.19

Conclusions

Disease activity improved with changes in DMARD therapy; however, the addition of bDMARDs were associated with significantly shorter time to remission. This study uses novel data collection techniques to replicate findings from prior observational studies in a much larger and contemporaneous cohort of patients under conditions of routine clinical practice.



The addition of bDMARDs were associated with significantly shorter time to remission.

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3. Treatment Patterns in Large Vessel Arteritis (Giant Cell Arteritis and Temporal Arteritis): Findings from a Large Contemporaneous Real-World Cohort in the US

Tom Brecht, Zhaohui Su, Richard Gliklich, Vandana Menon
ACR/ARHP Annual Meeting. November 4-8, 2017. San Diego, CA.

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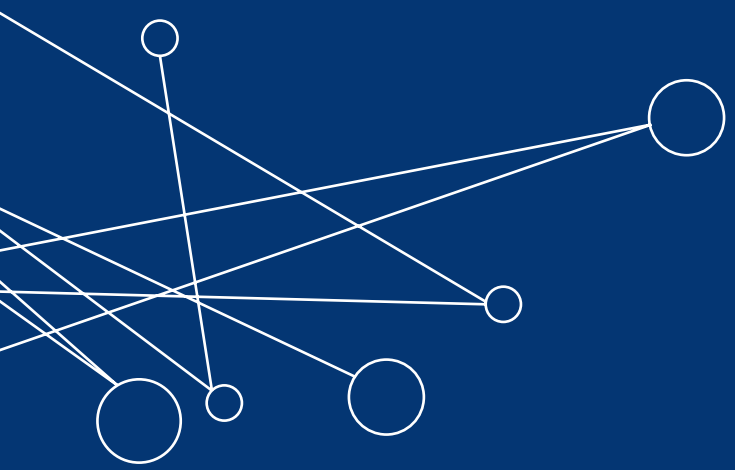


Background

Giant cell arteritis (GCA) is the most common form of primary systemic vasculitis with annual incidence as high as 27 per 100,000 in persons over the age of 50 years. Key issues in management after a diagnosis of GCA include prompt initiation of therapy, prevention and treatment of adverse effects related to treatment, and close monitoring for disease flares. Glucocorticoids are the mainstay of therapy and are used for induction and maintenance of remission. However, there is little consensus on the optimal treatment strategies for GCA. We present treatment patterns in a large real-world population of patients with GCA managed by rheumatologists across the US.

Methods

The OM1 platform collects, links, and leverages, structured and unstructured data from electronic medical records (EMR) and other sources in an ongoing and continuously updating manner to create a next generation registry — a novel approach to real world evidence. The OM1 GCA Cohort includes data who met our definition of at least two GCA related diagnosis codes [ICD-10: M31.6, M31.5, M31.4; ICD-9: 446.7, 446.5] within a 1 year period, treated by rheumatologists.

Patients characteristics, including demographics, comorbidities and medication exposures are based on all data after GCA diagnosis dates. Baseline diagnosis test is the first available test after GCA diagnosis date. The changes in diagnosis tests are the differences between the first two test results that are at least 30 days apart during the study period.

OM1 GCA Patient Cohort

Met definition of at least the following:

ICD-10	ICD-9
M31.4 *Aortic arch syndrome*	**446.5** *Giant cell arteritis*
M31.5 *Giant cell arteritis with polymyalgia rheumatica*	**446.7** *Takayasu's disease*
M31.6 *Other giant cell arteritis*	

Results

The cohort included 1,567 patients with a mean age of 73±10 years, three quarters were Caucasian (78%) and female (76%). Median follow up time was 24 months with a median of 7 rheumatology ambulatory encounters **[Table 1]**.

Nearly a third of the cohort had a concomitant diagnosis of polymyalgia rheumatica (33%) and 60% had rheumatoid arthritis. Only 6% of patients had a documented temporal artery biopsy [**Figure 1**].

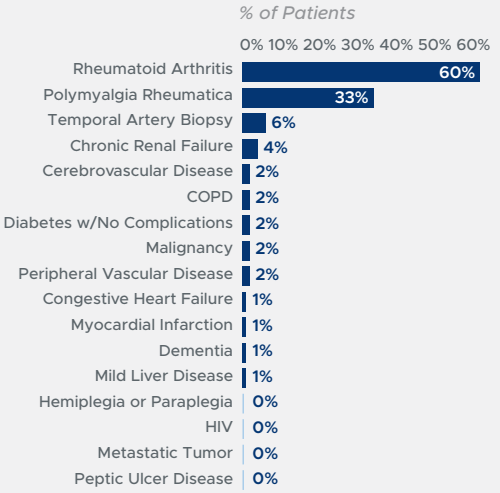
Table 1. Patient Characteristics

Characteristic	Patients with GCA (n=1,567)
Demographics	
Age [mean ± sd]	73 ± 10 years
Median follow up time for cohort months	24 months
Female [n, %]	1,188 (76%)
Race [%]	
Caucasian	1,220 (78%)
African American	71 (5%)
Other	162 (10%)
Unknown	114 (7%)
Geographic Distribution [%]	
Midwest	205 (13%)
Northeast	265 (17%)
Southeast	884 (56%)
Southwest	55 (4%)
West	158 (10%)
Rheumatology encounters [median (Q1, Q3)]	7 (4,14)
Charlson Comorbidity Index (0-1, 2-4, 5-9, ≥10)	0-1: 1,376 (88%) 2-4: 180 (11%) 5-9: 11 (<1%) ≥10: 0

Table 2. Disease Activity Markers

Characteristic	Patients with GCA (n=1,567)
Disease Activity	
ESR (mm/h): % of patients with	
1 measurement	796 (51%)
2+ measurements	407 (26%)
ESR at baseline median (Q1-Q3)	21 (8, 48)
Change in ESR (mm/h): Median (Q1-Q3)	0.5 (-1.4, 3.7)
Median (Q1-Q3) time in days between ESR labs	50 (30, 91)
CRP (mg/L): % of patients with	
1 measurement	629 (40%)
2+ measurements	548 (35%)
CRP at baseline median (Q1-Q3) (mg/L)	1 (0.3, 4)
Change in CRP (mg/L): Median (Q1-Q3)	0 (-0.1, 0.2)
Median (Q1-Q3) time in days between CRP labs	49 (30, 91)
% of patients with a least one Patient Reported Global Score	407 (26%)
Baseline Global Score: Median (Q1-Q3)	3 (1, 6)
Change in Global Score: Median (Q1-Q3)	0 (-1.5, 1.5)
% of patients with a least one Patient Reported Pain Score	400 (26%)
Baseline Pain Score: Median (Q1-Q3)	3 (0.5, 6)
Change in Pain Score: Median (Q1-Q3)	0 (-1.0, 1.0)

Figure 1. % of Patients with Comorbid Conditions



Results (continued)

About half of the patients had at least one erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) measurement. Median ESR at baseline was 21mm/hr (Q1, Q3: 8, 48) and median (Q1, Q3) CRP was 1mg/L (0.3, 4.0). The majority of patients received glucocorticoids (85%), 22% were treated with methotrexate, 8% with hydroxychloroquine, 5% with aspirin, 5% with tocilizumab and 3.5% with azathioprine [**Figure 2**].

14% were treated with more than one drug concurrently. Patient reported pain scores were available in 26% of the patients with a median duration of 6 months between first and last assessment. Changes in ESR, CRP, pain and global scores are not statistically different (P>0.05) among patients treated with the 3 most common medications [**Figure 3**].

Figure 2. Treatment exposure for GCA

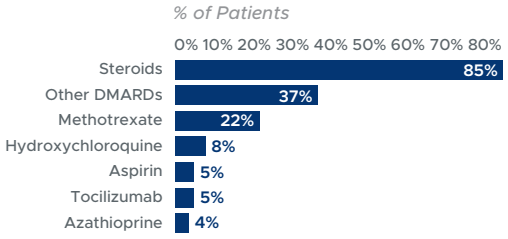
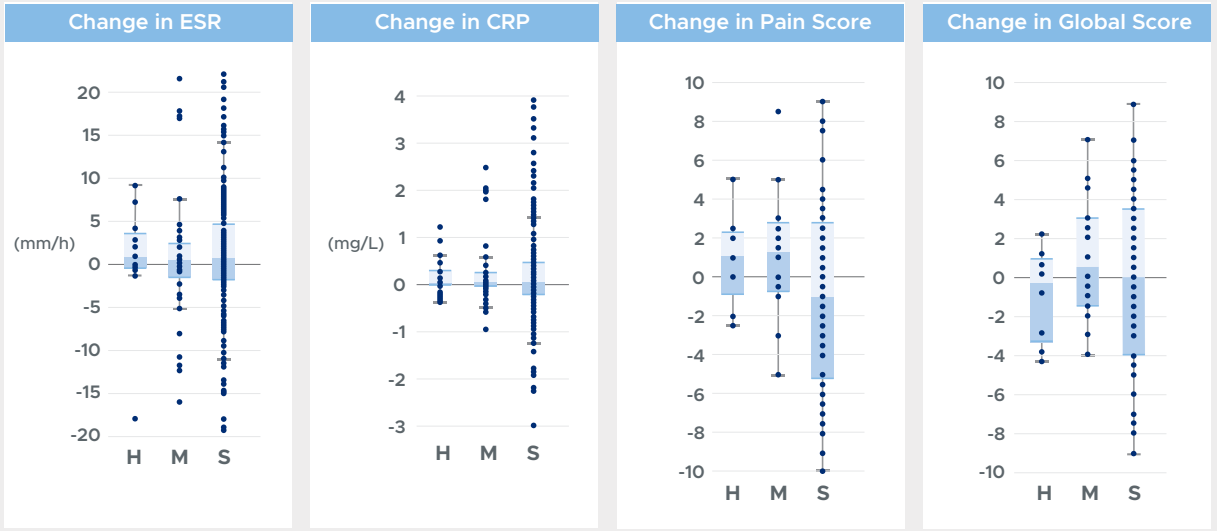


Figure 3. Changes in ESR, CRP, Pain Score, and Global Score

H = Hydroxychloroquine **M** = Methotrexate **S** = Steroids

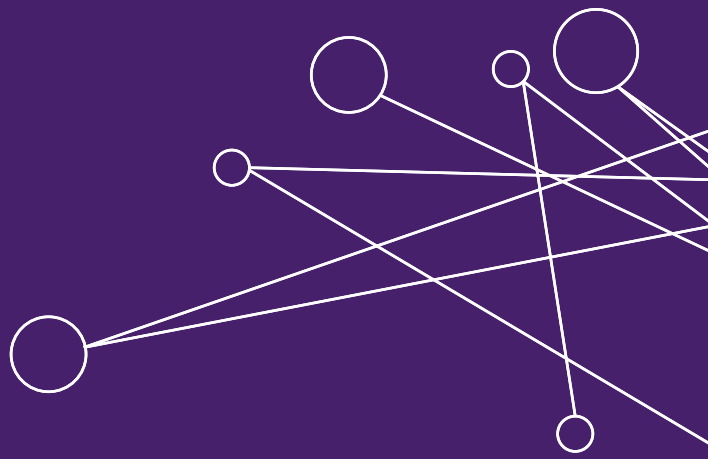


Conclusions

We present findings from a large, representative, cohort of real-world patients seen in routine clinical practice.

There are wide variations in patient profile and treatment practices and glucocorticoids remain the most common treatment with a minority of patients receiving steroid sparing agents. This may reflect the lack of clarity around value of additional steroid-sparing agents to avoid the common glucocorticoid adverse effects and to reduce time to remission.

Disease activity measures were not routinely performed and only half of the patients had at least one inflammatory marker measurement and less than a quarter had an assessment of pain. Given the potential side effects of commonly used medications, functional assessments of symptom improvement may be a useful and critical tool to evaluate effectiveness of therapy and guide clinical decision-making.



Functional assessments of symptom improvement may be a useful and critical tool to evaluate effectiveness of therapy and guide clinical decision-making.

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4. A Simple Predictive Score for Pre-Admission Identification of Risk of 30-day Hospital Readmission or Death in Heart Failure

Zhaohui Su, Tom Brecht, Richard Gliklich, Vandana Menon; Journal of the American College of Cardiology, Volume 69, Issue 11, Supplement, 21 March 2017, Page 772

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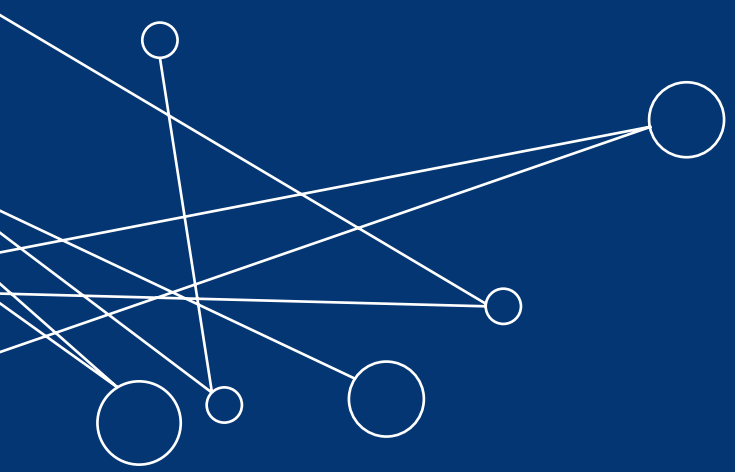


Background

Readmissions after heart failure (HF) are the focus of pay-for-performance initiatives. Most risk calculations for HF patients incorporate inpatient data. Early and accurate identification of patients at risk for readmissions may improve quality and reduce cost of care.

Methods

200,000+
Patients with heart failure

24,615
HF patients with at least 1 related hospital admission

1-10
Range of risk score with 10 indicating highest risk

5+
Patients with 5+ risk score are considered at risk for readmission

The OM1 data platform links together structured and unstructured clinical, administrative and other data from a large number of sources at the individual level to construct patient journeys, measure health outcomes and benchmark care.

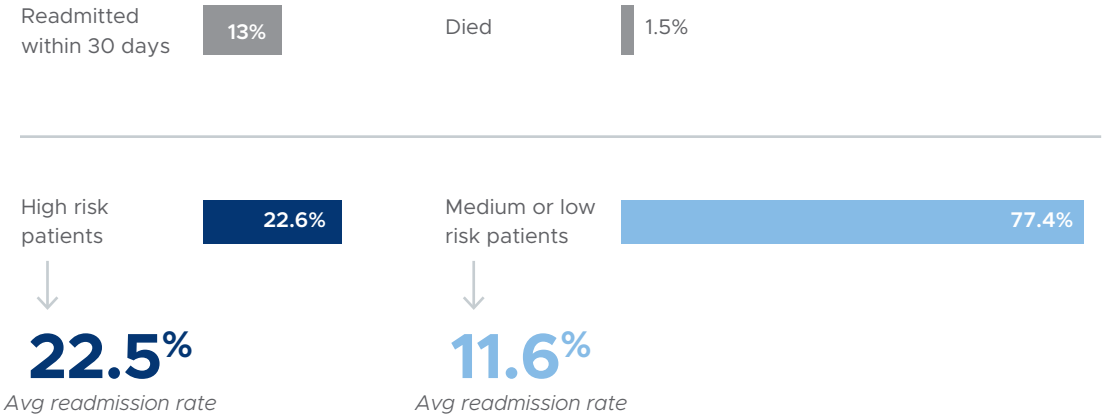
Prescriptive analytics resulting from machine and deep learning are used to identify actions that clinicians can take to avoid adverse events or to improve outcomes as part of learning health systems. OM1 Linked Data contains linked claims and EMR data from tens of millions of US patients. Of ~200,000 patients with HF, 24,615 met study criteria of at least 1 HF-related hospital admission and at least 6 months data preceding that admission.

Logistic regression, random forests, classification and regression trees were used to identify pre-admission predictors of 30-day readmission or death. Models were built in a training set with 67% randomly selected patients and validated in the remaining 33% patients. We computed the simple risk score by adding the assigned weights to each predictor based on the parameter estimates from the logistic regression. The risk score ranged from 1 to 10, with 10 indicating the highest risk. In the weighted analysis, the weights were the number of patients within the same risk score stratum.

Results

Of the 24,615 patients with index HF hospitalization, 3,109 (13%) were readmitted within 30 days and 365 (1.5%) died. Number of hospitalizations in the previous year, healthcare utilization in the previous year, Charlson comorbidity index, and months since last hospitalization were the strongest predictors.

The risk score was highly correlated with the readmission rate (R2=0.94). Patients with a risk score of 5 or higher were considered at high risk for HF readmission. In the validation set, 1,855 (22.6%) patients were at high risk, with an average readmission rate of 22.5%. This compared to 6,351 (77.4%) patients at medium or low risk, with an average readmission rate of 11.6%. The overall mis-classification rate in the validation set was 26.5%.

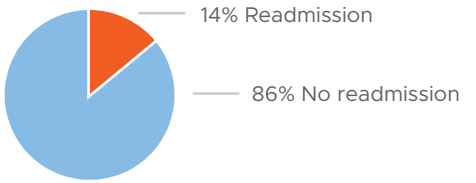


Results (continued)

Table 1. Patient Characteristics at the Time of Index Admission

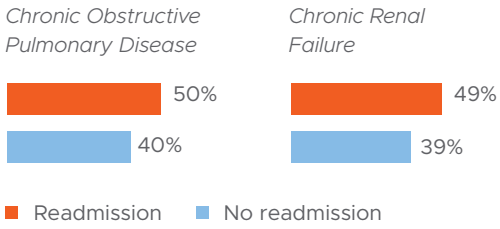
Pre-Admission Characteristics		30-Day Readmission: Readmission N=3,474	30-Day Readmission: No Readmission N=21,141	Total N=24,615
Gender n (%)	Female	1,702 (49%)	10,224 (48%)	11,926 (48%)
	Male	1,737 (50%)	10,463 (49%)	12,200 (50%)
Age (years) at index hospitalization	Mean (SD)	70 (13)	71 (13)	71 (13)
Hospitalizations within 12 months prior to index hospitalization	0	1,601 (46%)	13,024 (62%)	14,625 (59%)
	1-3	1,586 (46%)	7,553 (36%)	9,139 (37%)
	4-7	245 (7%)	531 (3%)	776 (3%)
	8	42 (1%)	33 (0%)	75 (0%)
Interval between most recent prior hospitalization and index hospitalization	1-2 months	1,438 (41%)	5,769 (27%)	7,207 (29%)
	3-4 months	670 (19%)	4,335 (21%)	5,005 (20%)
	5-6 months	572 (16%)	4,282 (20%)	4,854 (20%)
	>6 months	794 (23%)	6,755 (32%)	7,549 (31%)
Chronic Obstructive Pulmonary Disease		1,737 (50%)	8,383 (40%)	10,120 (41%)
Chronic renal failure		1,714 (49%)	8,337 (39%)	10,051 (41%)
Charlson comorbidity index at index admission	0-1	512 (15%)	5,007 (24%)	5,519 (22%)
	2-4	1,369 (39%)	9,052 (43%)	10,421 (42%)
	5-9	1,450 (42%)	6,609 (31%)	8,059 (33%)
	10	143 (4%)	473 (2%)	616 (3%)
Low diastolic blood pressure (mmHg) within 12 months prior to the index admission	<80	2,849 (82%)	17,456 (83%)	20,305 (83%)
	80-89	463 (13%)	2,838 (13%)	3,301 (13%)
	90-99	122 (4%)	673 (3%)	795 (3%)
	100	38 (1%)	170 (1%)	208 (1%)
Healthcare utilization within 12 months before index admission*	<10	370 (11%)	4,090 (19%)	4,460 (18%)
	10-19	474 (14%)	3,686 (17%)	4,160 (17%)
	20	2,630 (76%)	13,365 (63%)	15,995 (65%)

*Defined as number of service codes in claims



71yrs

Mean age of HF patient



Results (continued)

Figure 1. Odds Ratios for Predictors of HF Readmission

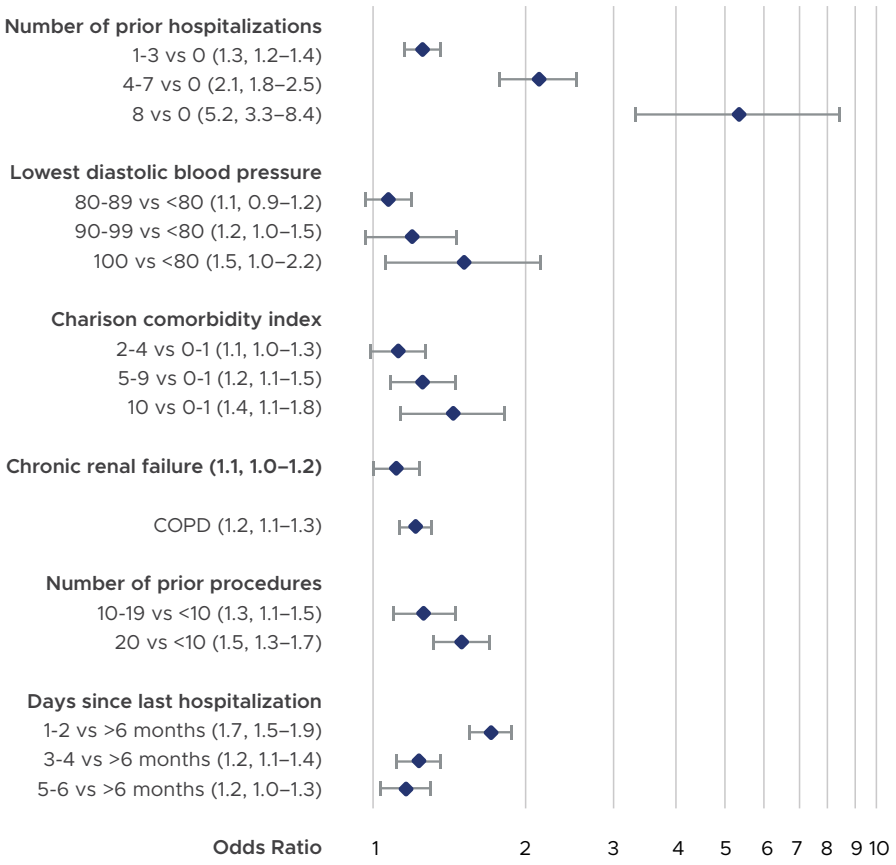


Figure 2. Correlation between Risk Score and Readmission Rate

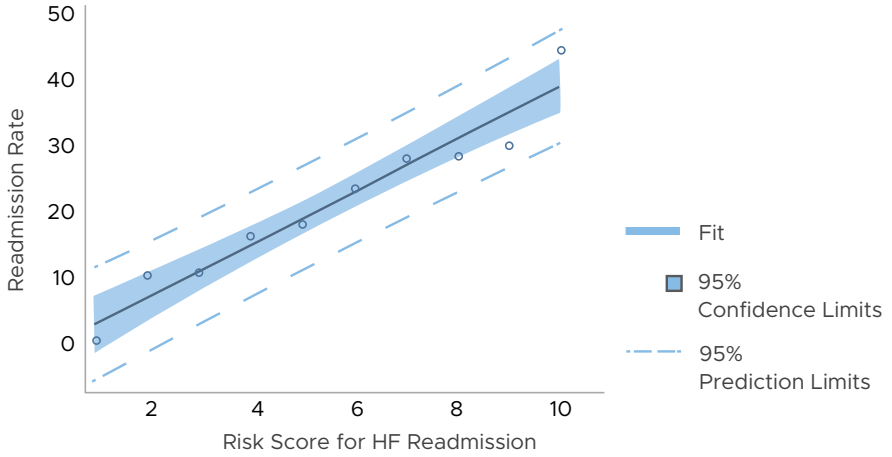
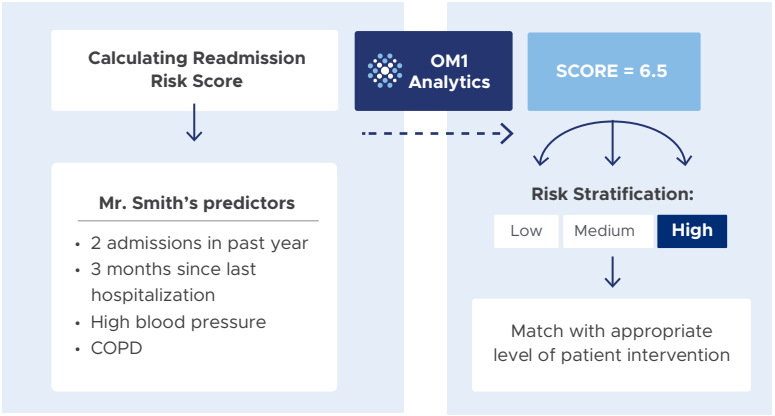
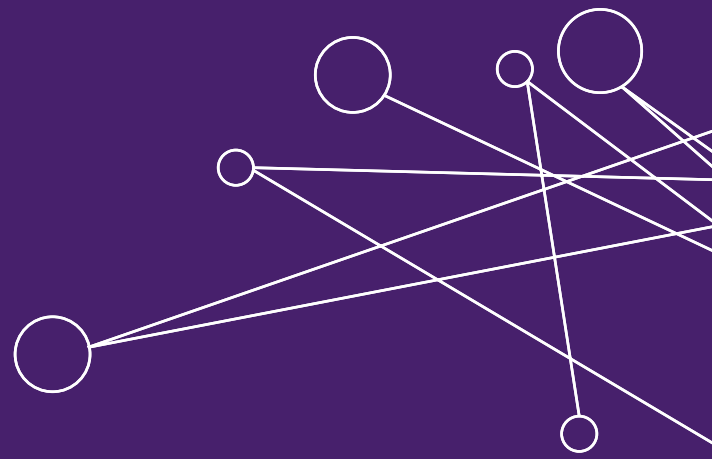


Figure 3. Application of Risk Score



Conclusions

We developed a simple score using data elements routinely collected in an outpatient setting to identify HF patients at risk for readmissions. Our model correctly predicted 30-day readmission or death prior to index HF admission, in at least 7 out of 10 randomly selected patients.



We correctly predicted 30-day readmission or death prior to index HF admission, in at least 7 out of 10 randomly selected patients.

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5. Machine Learning Generated Risk Model to Predict Unplanned Hospital Admission in Heart Failure

O'Donovan F, Brecht T, Kekeh C, Su Z, Boussios C, Menon V, Gliklich R, Fonarow GC; AHA Scientific Sessions. November 11-15, 2017. Anaheim, CA.

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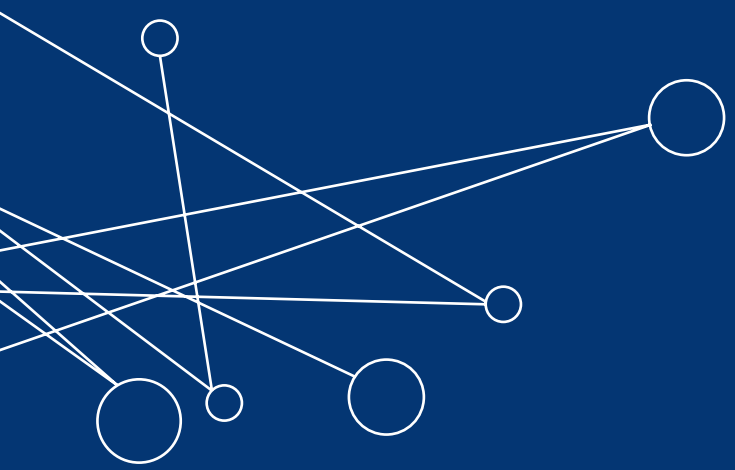
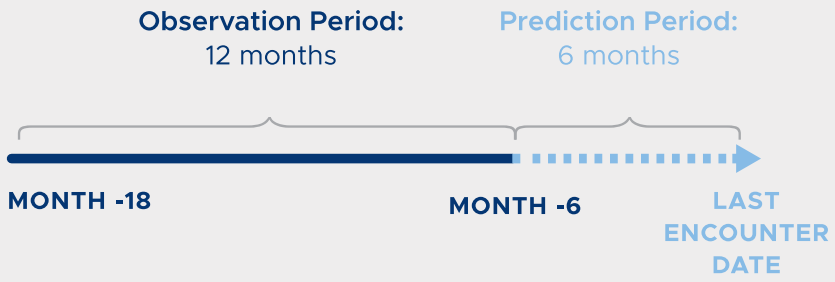


Background

Heart failure (HF) is a leading cause of hospitalization. There are few tools to accurately identify patients at high risk for unplanned admission in the outpatient setting. We used machine learning (ML) on outpatient electronic medical records and medical claims to develop a HF specific predictive model.

Methods

The OM1™ Cardiology data warehouse contains deep clinical and claims data on patients seen in cardiology practices across the US. HF Patients with at least 18 months of data (July 2013 to December 2016) were included, with the last 6 months serving as the prediction period. The outcome was unplanned admission due to HF during the prediction period.



ML methods (Random Forests, Xgboost, and Treenet) were used to examine the association between predictive variables collected in the initial observation period and the binary outcome (unplanned admission versus no unplanned admission) and to identify high value predictors. We followed the definition of unplanned admission as described by Centers for Medicare & Medicaid Services. To facilitate interpretation and comparison with literature, important predictors identified via ML were entered into a multivariable logistic regression model to derive HF risk scores. Patients were randomly assigned to training (70%) and validation (30%) sets.

One of the key predictive features is the OM1 Medical Burden Index, which is a standardized measure of the combined effect of current and prior conditions and treatments on current health status, on 0–1000 scale. It has been generated from extensive analysis of OM1's longitudinal patient cohort (n>175M).

Results

48,761
HF patients

2,770
Unplanned admissions

49%
Male

54%
Caucasian

71yrs
Median age

A total 48,761 patients with 2,770 unplanned admissions were included in the analysis; median age was 71 years, 49% were men, and 54% were white (**Table 1**).

The top 5 predictors from the training set, as determined by machine learning, were OM1 medical burden index (ML derived scores on a 0–1000 scale, leveraging all available prior history), number of services in the previous year, number of hospitalizations in the previous year, time since last hospitalization, and Charlson comorbidity. These 5 predictors were used to derive HF risk scores in the validation set of 14,546 patients (**Table 2**).

Table 1. Patient characteristics during the 12-month observation period, stratified by the admission status during the 6-month prediction period

Patient Characteristics		Admission N=2,770	No admission N=45,991	Total N=48,761
Gender n (%)	Female	1,441 (52%)	23,385 (51%)	24,826 (51%)
	Male	1,329 (48%)	22,606 (49%)	23,935 (49%)
Age (years)	Mean (SD)	68 (13)	70 (12)	70 (12)
	Median (Q1-Q3)	69 (69-78)	71 (62-79)	71 (62-79)
OM1 medical burden index	Mean (SD)	24 (42)	10 (23)	11 (25)
	Median (Q1-Q3)	13 (5-27)	4 (1-11)	5 (1-11)
Charlson comorbidity index	Mean (SD)	3.9 (2.2)	2.7 (1.8)	2.8 (1.9)
	Median (Q1-Q3)	4 (2-5)	2 (1-4)	2 (1-4)

Table 2. The OM1 medical burden index is the single most predictive variable in univariate analysis

Variable name	C statistic[1]	Odds ratio	95% CI
OM1 medical burden index	0.72	1.14	1.08-1.21
Number of services in the past 12 months	0.71	1.04	1.02-1.06
Number of hospitalizations in the past 12 months	0.70	1.22	1.18-1.25
Time since last hospitalization	0.70	1.16	1.05-1.31
Charlson comorbidity index	0.65	1.08	1.03-1.12

[1] With each variable included as the only predictor in the model

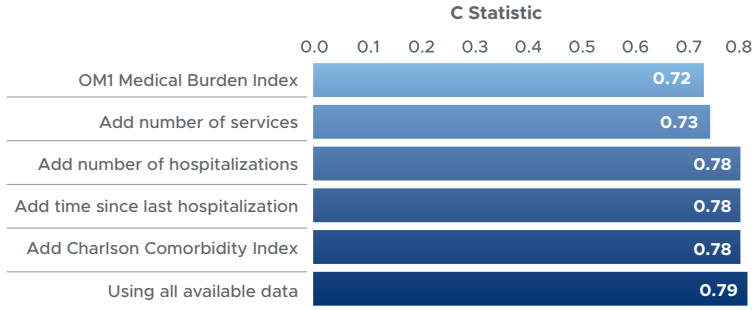
Results (continued)

Using the OM1 medical burden index as the single predictor, the model had a C statistic of 0.72. Adding the other top 4 predictors increased the C statistic to 0.78. Using all available data only slightly improved the C statistic to 0.79. All C statistics reported here were from the validation set (**Figure 1**).

In the validation set, 825 (5.7%) were hospitalized during the 6-month prediction period. Using the risk score as a single predictor, our model correctly predicted outcomes for 12,189 (84%) patients. All top 5 predictors identified by machine learning were statistically significant in the regression model (**Figure 2**).

The odds ratios in Figure 2 represent one unit increase of OM1 medical burden index on a log scale, every 20 services in the past 12 months, time since last hospitalization in quarters, and Charlson comorbidity index. Fixing specificity at 50%, the machine learning model had high sensitivity (85%) in predicting unplanned hospitalization in the next 6 months (**Figure 3**).

Figure 1. Addition of other machine learning-generated predictive features to the OM1 medical burden index improved the predictive performance (C statistic: 0.72 to 0.79)



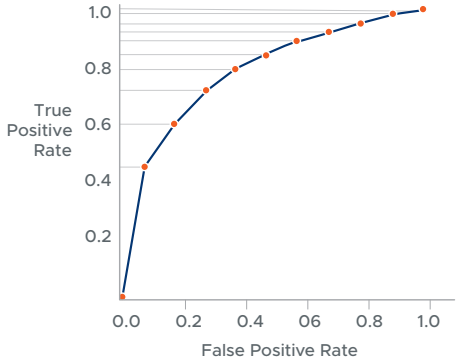


Figure 2. Odds ratios for the most influential predictive features in multivariable analysis

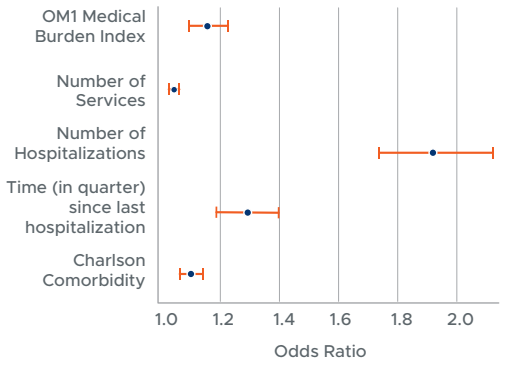
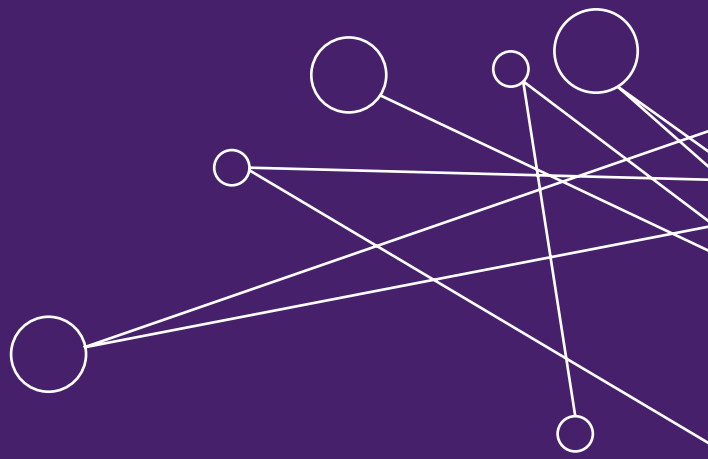


Figure 3. Receiver operating characteristics of the machine learning model (C statistic: 0.79)

Conclusions

We demonstrated the utility of machine learning in leveraging variables readily available in an outpatient EMR and medical claims to predict hospitalizations in 8 out of 10 patients (C Statistic: 0.79). When integrated into the clinical workflow, such tools may offer the ability to focus resources on patients at highest risk for unplanned admission.



We correctly predicted hospitalizations in 8 out of 10 patients using machine learning.

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6. Machine Learning Enhanced Predictions of Hospital Readmission or Death in Heart Failure

Su Z, Brecht T, O'Donovan F, Boussios C, Menon V, Gliklich R, Fonarow GC;
AHA Scientific Sessions. November 11-15, 2017. Anaheim, CA.

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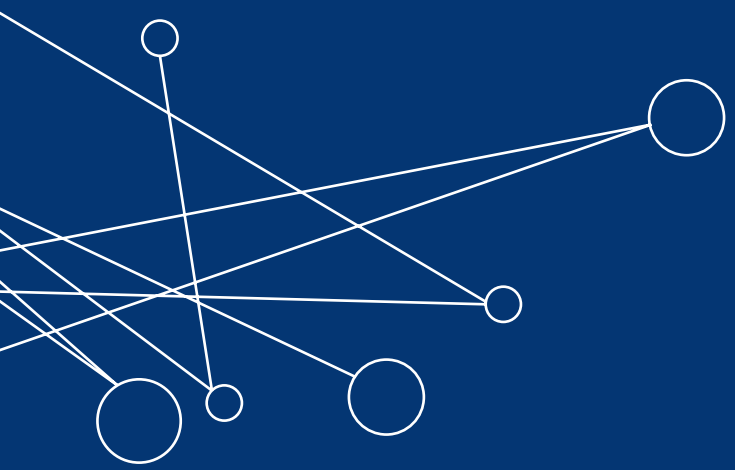


Background

Readmissions are common, costly and often preventable. The LACE risk score is an established index to quantify the risk of readmission or death. We used machine learning to develop a Heart Failure (HF) specific predictive tool.

Methods

The OM1™ Cardiology data warehouse contains deep clinical and claims data on patients seen in cardiology practices across the US. Patients with HF, hospitalized between October 2014 and Sept 2016, with at least 12 months of data before the index admission, and 30 days of data post discharge, were included. The unit of analysis was hospitalization. The outcome was all-cause unplanned readmission as defined by Centers for Medicare & Medicaid Services. Those index admissions occurring before April 2016 (~70%) were used as the training set and the remainder as the validation set. Predictive features were developed by machine learning for the training set, and the performance of the resultant OM1 HF readmission risk score (on 0–100 scale; abbreviated as OM1 risk score below) was compared with that of the LACE risk score for the validation set.

One of the key predictive features is the OM1 Medical Burden Index, which is a standardized measure of the combined effect of current and prior conditions and treatments on current health status, on 0–1000 scale. It has been generated from extensive analysis of OM1's longitudinal patient cohort (n>175M).

Patients with a LACE risk score of 10 or greater were considered at high risk of readmission. In comparison, patients with an OM1 risk score of 15 or greater were at high risk.

10+
LACE risk score considered at high risk for readmission

15+
OM1 risk score considered at high risk for readmission

Results

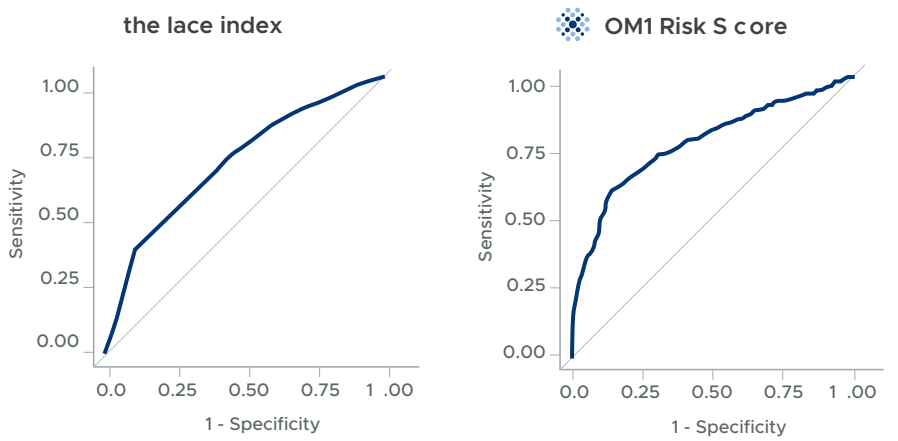
The study included 14,065 HF related hospitalizations with 3,502 (25%) unplanned readmissions or death within 30 days of discharge; median age was 67 years, 53% were women, and 46% were white (**Table 1**).

OM1 medical burden index, admission via the emergency department (ED), number of ED visits in the 6 months prior to index hospitalization, and age were the top 4 predictors determined by machine learning and were used to derive OM1 risk scores in the validation set of 4,260 index hospitalizations. The OM1 risk scores had a C statistics of 0.77 compared to 0.69 for LACE, in both the training and validation sets, respectively (**Figure 1**).

Table 1. Patient Characteristics Pre-admission through Discharge from the Index Admission

Patient Characteristics		30-day Readmission n=3,502	No Readmission n=10,563	Total n=14,065
Gender	Female n, (%)	1,826 (52%)	5,644 (53%)	7,470 (53%)
Race	White n, (%)	1,468 (42%)	4,946 (47%)	6,414 (46%)
	Black n, (%)	855 (24%)	2,199 (21%)	3,054 (22%)
	Other n, (%)	397 (12%)	1,354 (12%)	1,751 (12%)
	Not reported n	782 (22%)	2,064 (20%)	2,846 (20%)
Age (years) at index admission	Mean (SD)	63 (14)	67 (13)	66 (13)
	Median (Q1-Q3)	62 (54-74)	68 (58-77)	67 (57-77)
Length of stay (days)	Mean (SD)	3.8 (11.1)	6.8 (24.4)	6.1 (21.9)
	Median (Q1-Q3)	2 (1-4)	3 (1-5)	2 (1-5)
Admission via emergency department	n, (%)	2,188 (62%)	2,076 (20%)	4,264 (30%)
Charlson comorbidity index at index admission	Mean (SD)	6.5 (3.0)	5.7 (2.8)	5.9 (2.9)
	Median (Q1-Q3)	6 (4-8)	5 (4-7)	6 (4-8)
Number of ED visits in the 6 months prior to index admission	Mean (SD)	5.3 (9.6)	1.3 (2.2)	2.3 (5.5)
	Median (Q1-Q3)	2 (0-6)	1 (0-2)	1 (0-2)
OM1 medical burden index at discharge date from the index admission	Mean (SD)	72 (112)	28 (48)	39 (72)
	Median (Q1-Q3)	31 (13-71)	16 (7-32)	19 (8-39)

Figure 1. Receiver Operating Characteristic (ROC) Curves for the LACE index (C Statistic 0.69) and the OM1 Risk Score (C Statistic 0.77)



Results (continued)

The LACE risk score had a precision of 36% with 771 actual readmissions or death out of the 2,170 predicted. When matched with the LACE score precision, the OM1 model was more sensitive and correctly identified 887 (81%) of the total 1093 readmissions or deaths while the LACE risk score identified 771 (71%) (**Table 2**; **Figure 2**).

When dividing the OM1 risk scores into deciles at 10-point increments, the grouped OM1 risk scores were highly correlated with the readmission rates within deciles, with a strong linear trend of greater OM1 risk scores associated with higher readmission rates (R2=0.98, **Figure 3**).

Table 2. Distribution of Risk Prediction Scores

Risk Score	Risk Categories	30-day Readmission	No Readmission	Total
LACE Index	High risk	771 (71%)	1,399 (44%)	2,170 (51%)
	Low risk	322 (29%)	1,768 (56%)	2,090 (49%)
OM1 Risk Score	High risk	887 (81%)	1,587 (50%)	2,474 (58%)
	Low risk	206 (19%)	1,580 (50%)	1,786 (42%)

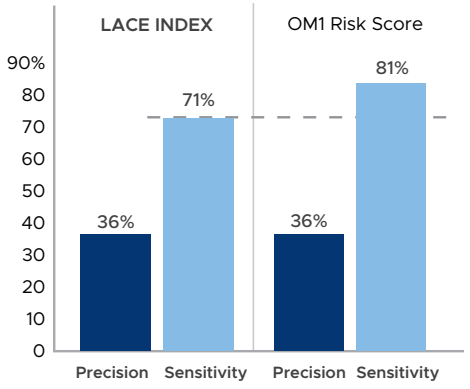
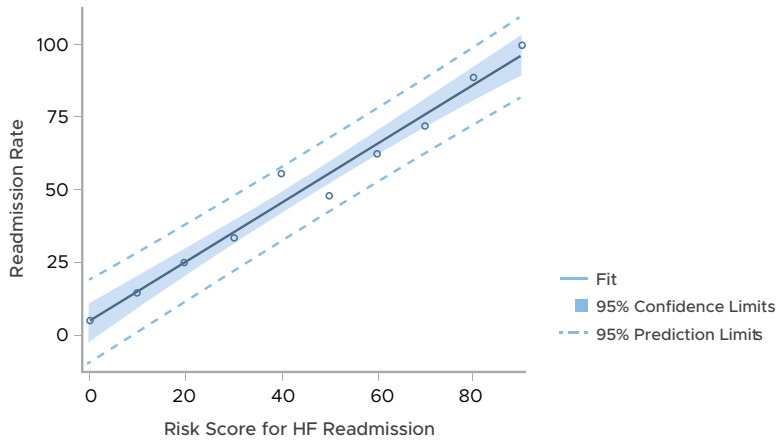


Figure 2. When Matched by Precision to the LACE Score (36%) the OM1 Risk Score (81%) was more Sensitive than the LACE Score (71%).

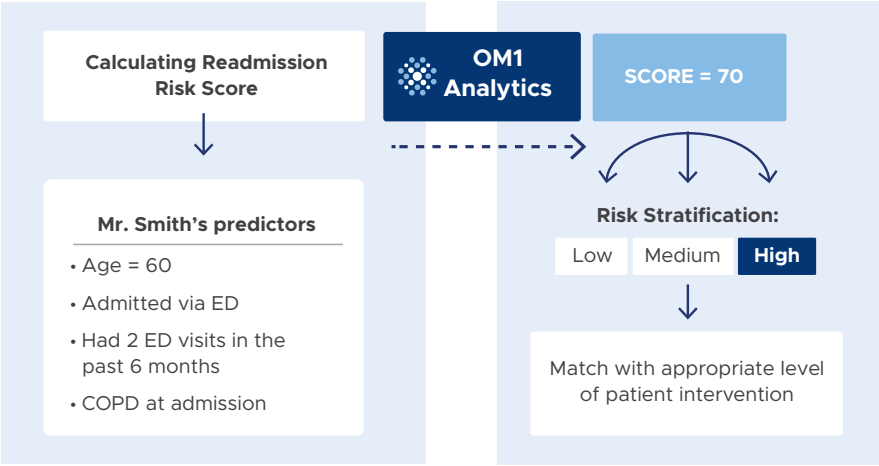
Figure 3. The OM1 Risk Score was Closely Correlated with the Observed Readmission Rate

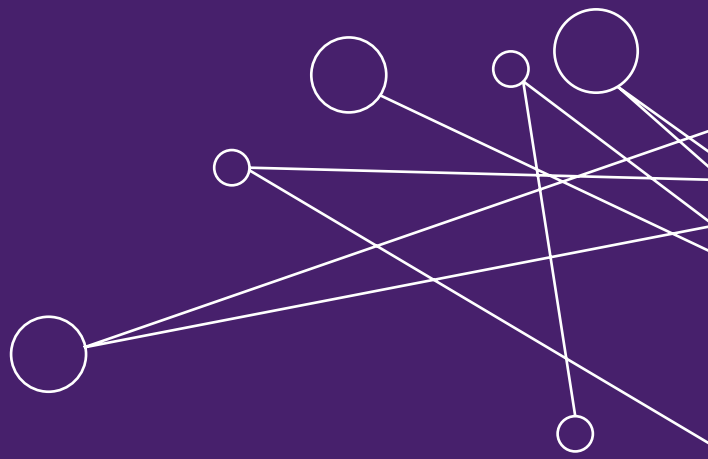


Conclusions

We present a new model to predict mortality and readmission at 30 days after an index admission for HF that has superior performance to a previously published claims-based model. Model performance is being further refined using laboratory and unstructured data. Integrating these predictive models into clinical workflow will permit timely interventions in high risk patients (Figure 4).

Figure 4. Clinical Application of the OM1 Risk Score





Integrating predictive models into clinical workflow will permit timely interventions in high risk patients.

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