

Analysis of Real-World Oral Prednisone Usage in Patients with Dermatomyositis Supports the Unmet Need for Additional Corticosteroid-Sparing Agents

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BACKGROUND

Dermatomyositis (DM) is a rare idiopathic inflammatory myopathy with skin involvement

Clinical manifestations may be severe and disabling

- Painful, itchy skin rashes on eyelids, cheeks, nose, back, upper chest, elbows, knees and knuckles
- Sudden or progressive proximal muscle weakness
- Hardened calcium deposits under the skin (calcinosis)
- Difficulty swallowing (dysphagia)
- Interstitial lung disease
- Increased cancer risk

Significant unmet need for new therapies

- Even with standard of care treatment, ~35% have recurrence after remission or chronic disease course >24 months*
- Steroids and immunomodulatory drugs are commonly used to treat DM, but can introduce chronic toxicities

*Bronner et al. Ann Rheum Dis, 2006.

Prednisone use*

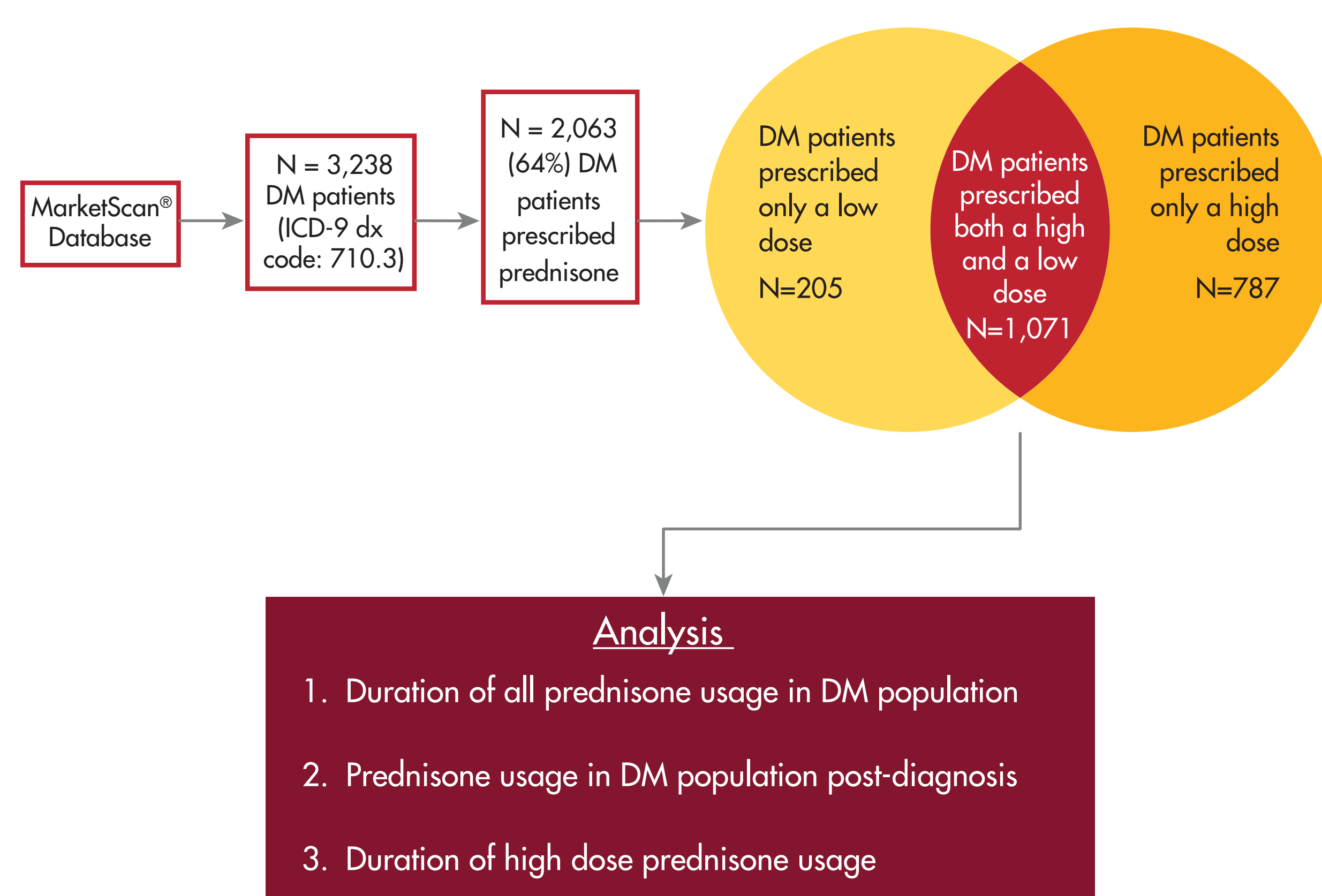
- Prednisone is used to treat a variety of disorders, including endocrine, rheumatic, dermatologic, allergic, ophthalmic, respiratory, hematologic, neoplastic, and nervous system disorders
- Very strict labeling instructions are provided to reduce the risk of harmful side effects associated with use
 - “The lowest possible dose of corticosteroid should be used to control the condition under treatment, and when reduction is possible, the reduction should be gradual”
- Adverse effects (AEs) of prednisone include, but are not limited to:

• Fluid and electrolyte disturbances	• Dermatologic	• Neurological
• Musculoskeletal	– Impaired wound healing	– Convulsions
– Weakness	– Fragile skin	– Vertigo
– Myopathy	– Sweating	– Headache
– Loss of muscle mass	• Metabolic	– Diabetes
• Gastrointestinal	• Ophthalmic	• Other
– Peptic ulcer	– Cataracts	– Hypersensitive reaction
– Pancreatitis	– Glaucoma	

*Prednisone tablets, USP package label

Study background

- Objective of the study was to assess the real-world use of oral prednisone via a closed commercial and Medicare supplemental claims databases to understand the unmet need for new corticosteroid-sparing agents for patients with dermatomyositis
- Statistical analysis was performed on the defined patient cohort using Anaconda Python



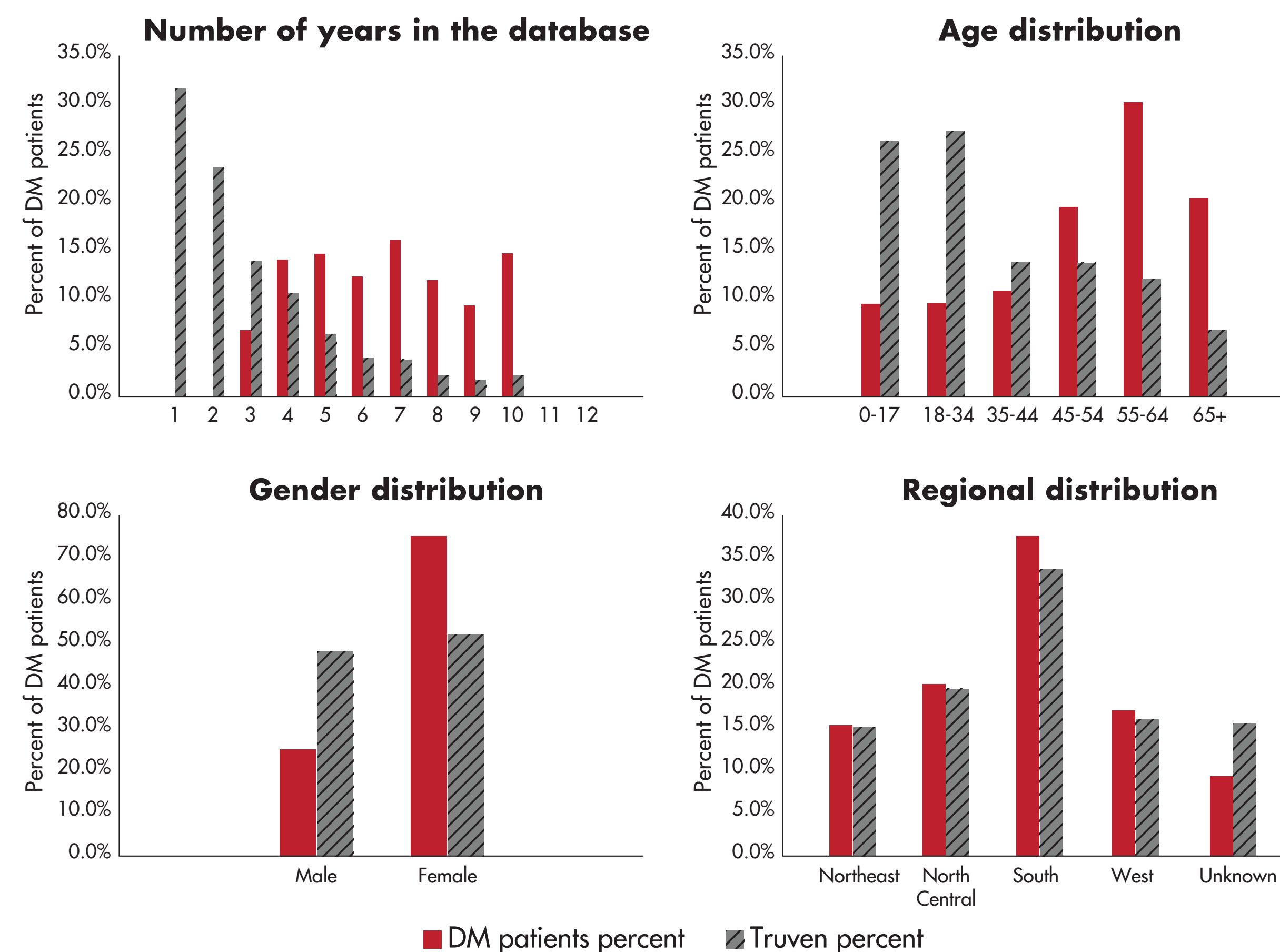
METHODS

- Truven MarketScan® database, containing patient level claims for ~148 million patients (2006 – Q1 2014)
- Dataset for the study contains commercial claims, Medicaid, and Medicare
- Patients with DM were defined as having the 710.3 ICD-9 diagnostic code within at least 3 separate months in their history
 - The DM diagnosis code was required to occur 3 times to increase the confidence that this was truly a DM patient population
- Patients with a minimum of 12 months of history before the first use of the DM ICD-9 code, and a max follow-up of 60 months, were included in the analysis (n = 3,238)
- The analysis examined patients who were prescribed prednisone
 - High dose prednisone ≥10mg/day
 - Low dose prednisone <10mg/day

RESULTS

DM patient population

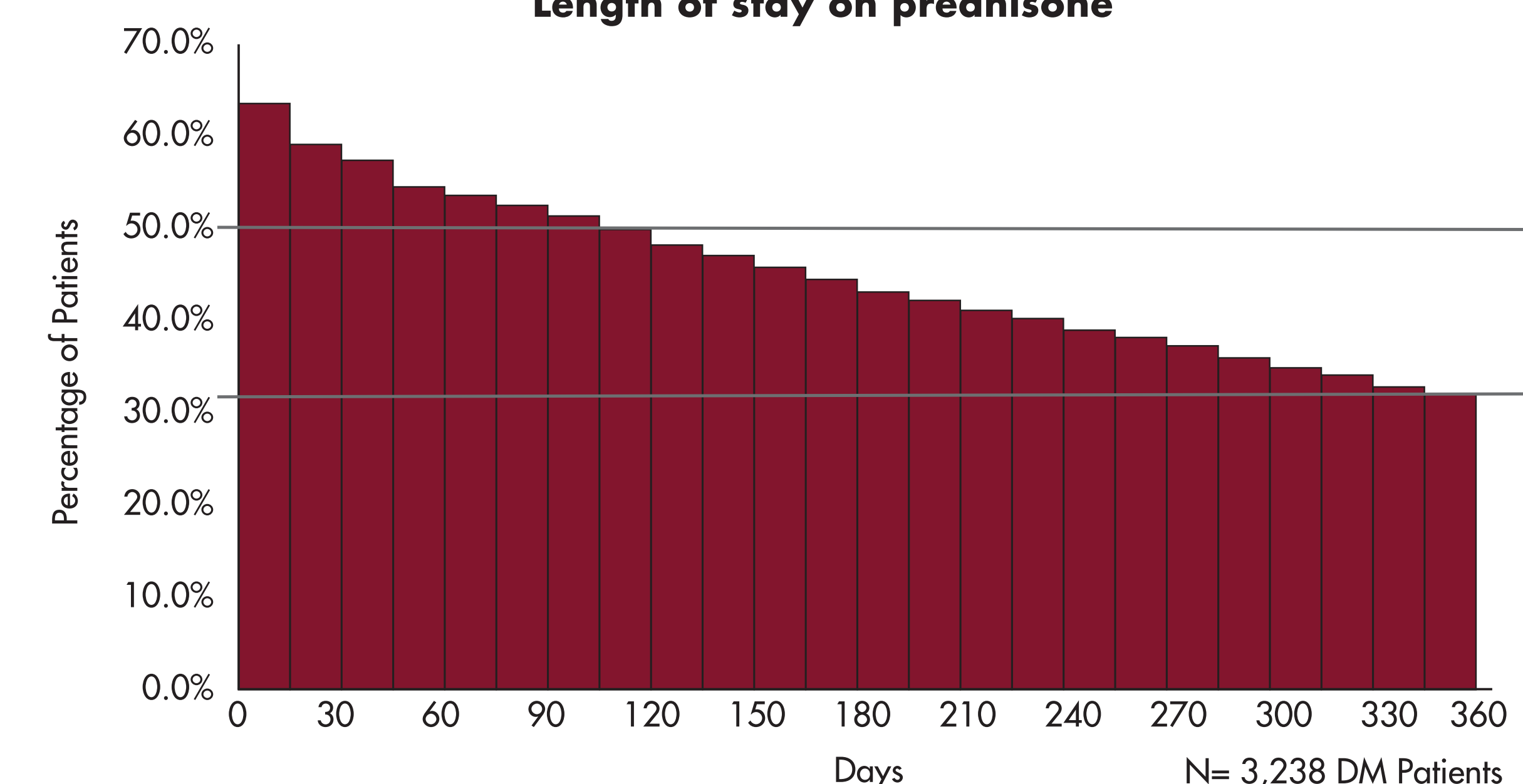
Demographics comparison between the 3,238 DM patients analyzed in this study and the Truven MarketScan® database



DM patients were commonly prescribed prednisone

- 64% of DM patients were prescribed prednisone at some point during their treatment
 - Specifically, 39% of DM patients were prescribed low dose prednisone at some point during treatment, and 57% were prescribed high dose prednisone at some point during treatment
- 50% of DM patients were prescribed prednisone for at least 120 days
- ~32% of DM patients were prescribed prednisone for one year

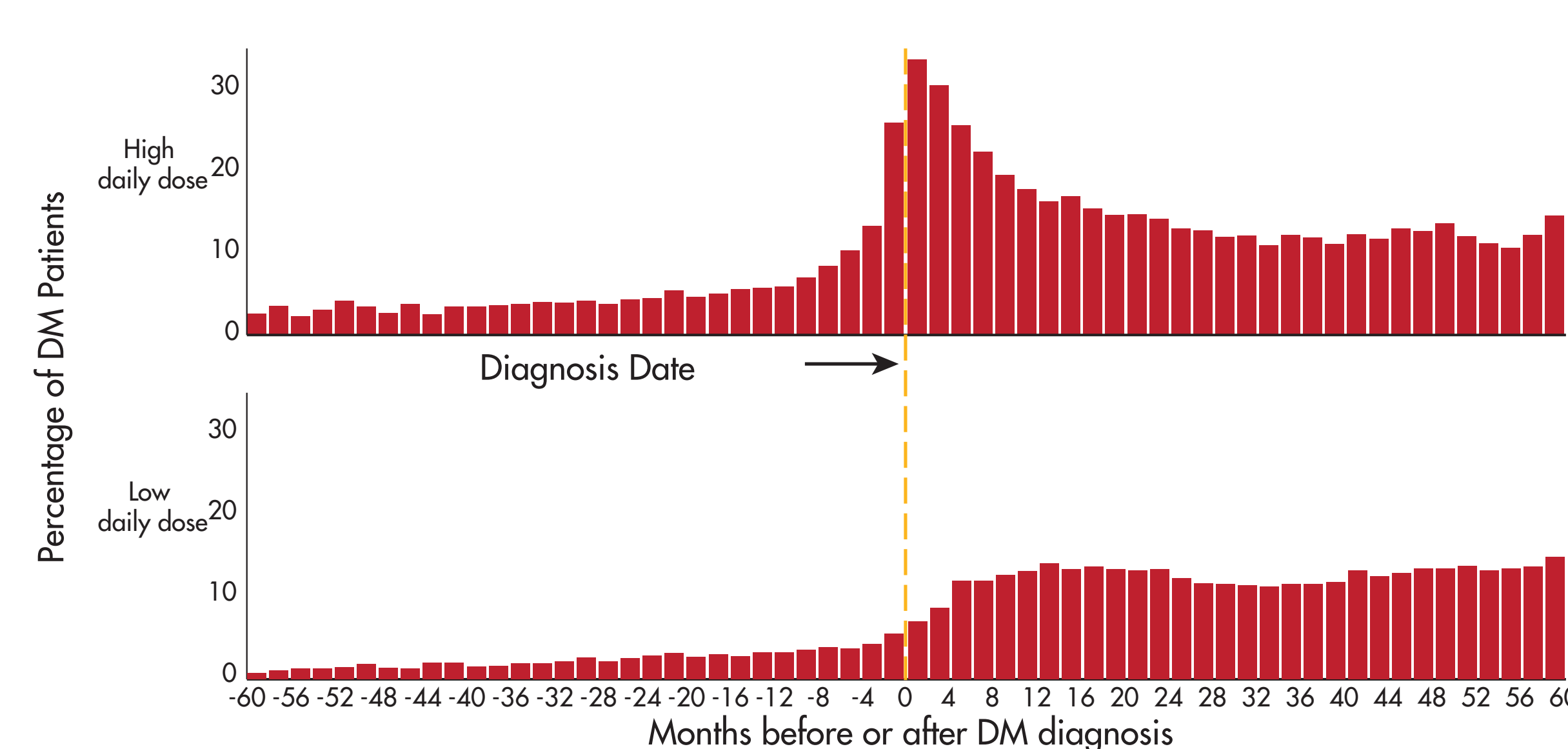
Length of stay on prednisone



High dose* prednisone used in ~33% of patients after DM diagnosis

- High dose prednisone was used in ~33% of DM patients in the first 4 months after diagnosis; this peak in percentage of patients prescribed high dose prednisone took two years post-diagnosis to stabilize
- Prednisone was used before and after diagnosis; ~25% of patients were prescribed high dose prednisone prior to diagnosis
- We saw a stable 3-fold increase in use of high dose prednisone after diagnosis compared to before diagnosis
- We saw a stable 4-fold increase in use of low dose prednisone after diagnosis compared to before diagnosis
- The percentage of patients prescribed high dose prednisone peaked within 2 months after diagnosis
- At any point in time post-diagnosis, there were approximately 10% of DM patients that were prescribed at least 10mg of prednisone per day

Percent of DM Patients Prescribed Prednisone

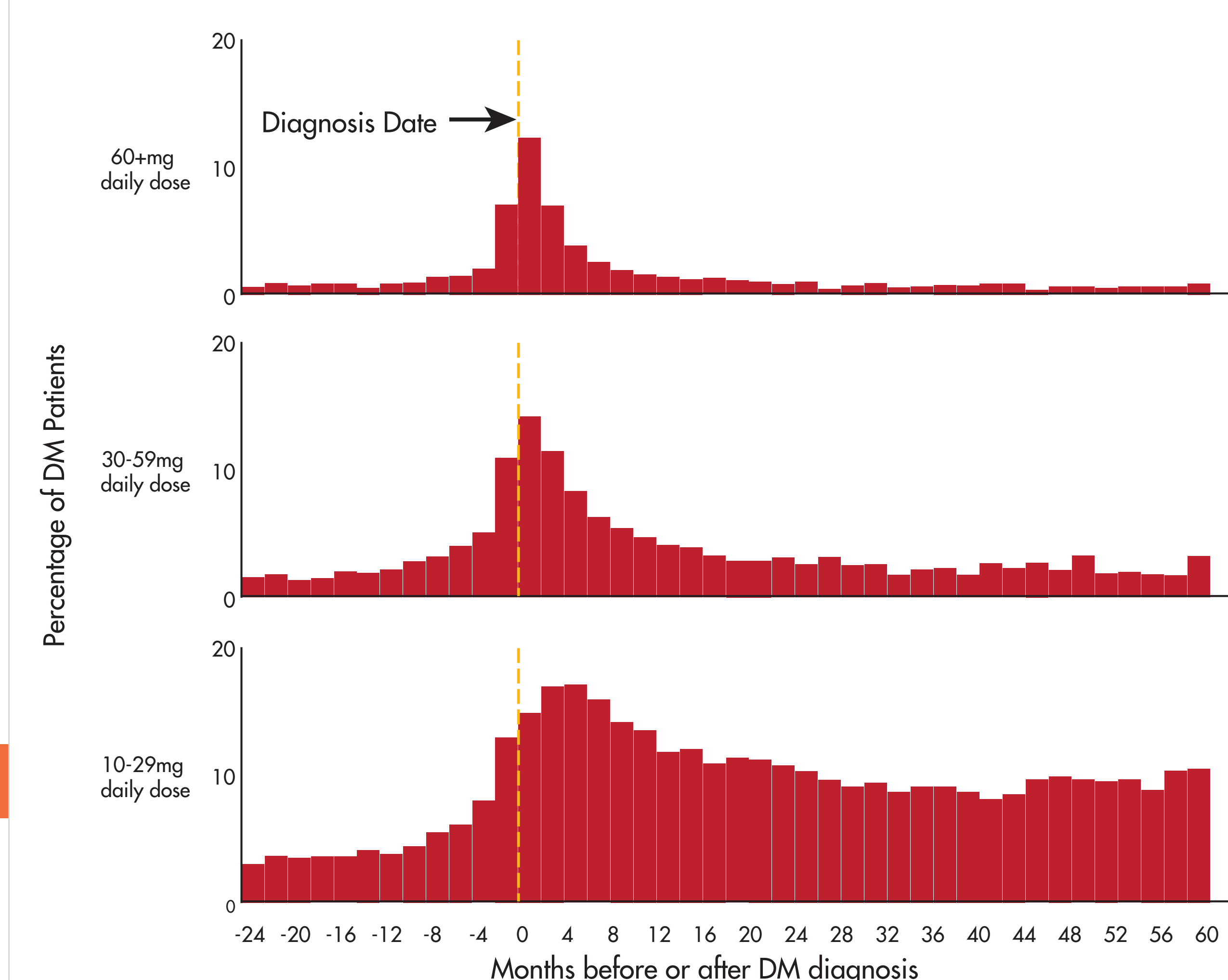


- Each bar represents an independent measurement of the percentage of the 3,238 DM patients at that point in time
 - The bar is not a representation of continuous use
- *High dose ≥10mg
N = 3,238 DM patients

Percentage of patients prescribed high dose* prednisone was highest around time of diagnosis

- ~33% of patients were on high dose prednisone around time of diagnosis
- Though some patients were on >60mg/day, the most common high dose was in the 10-29mg/day range

Percent of DM Patients Prescribed Prednisone



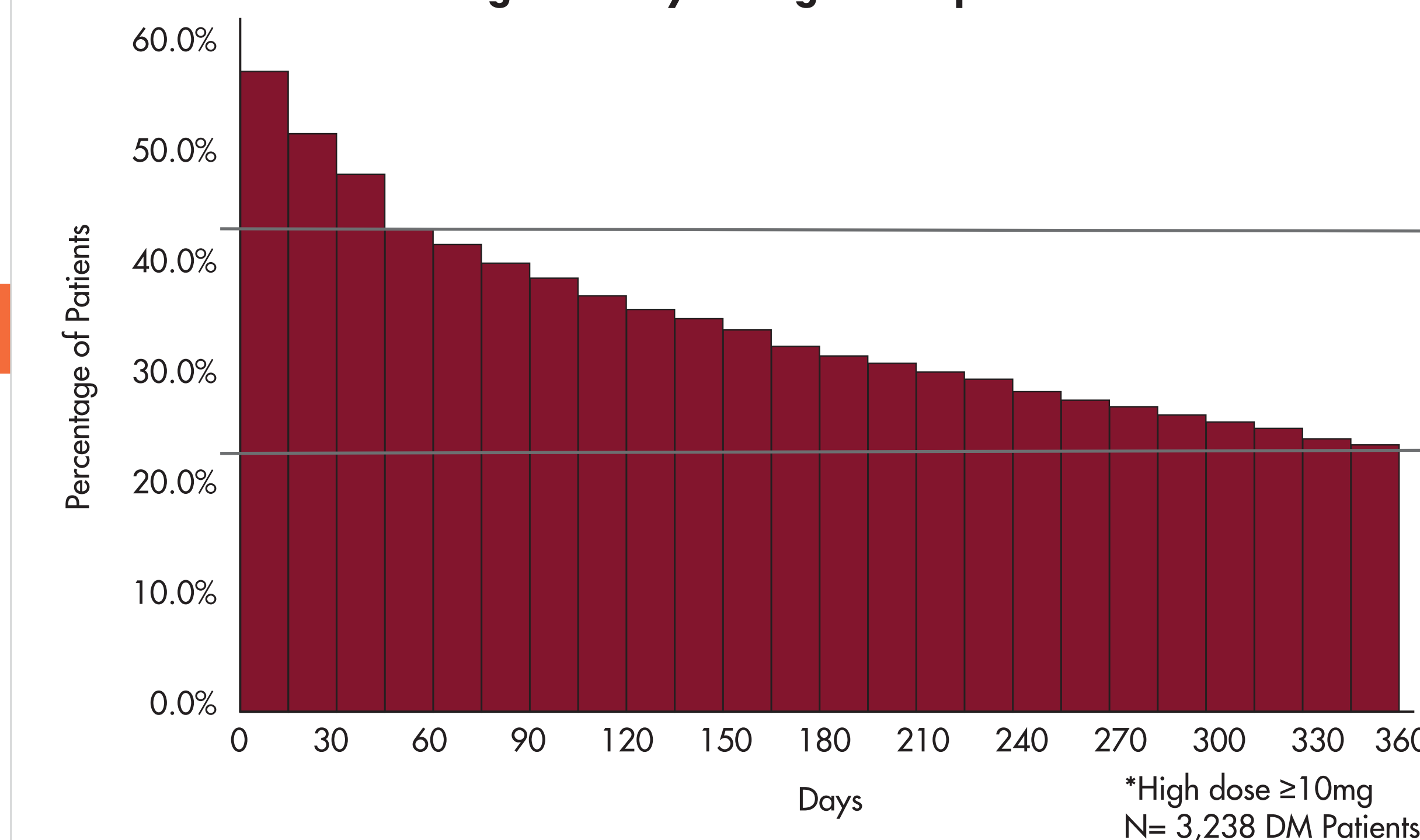
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*High dose ≥10mg
N= 3,238 DM Patients

One quarter of DM patients stayed on high dose* prednisone for one year

- ~43% of DM patients were prescribed high dose prednisone for at least 60 days
- ~24% of DM patients were prescribed high dose prednisone for one year

Length of stay on high dose prednisone



CONCLUSIONS

- Approximately half of DM patients were prescribed high or low dose prednisone for 120 days or longer
- The use of high dose prednisone was required to treat DM patients throughout all phases of their illness (pre-diagnosis, at diagnosis, and up to 5 years post-diagnosis)
- One quarter of DM patients were prescribed high dose prednisone for prolonged periods of time
- With high numbers of DM patients on chronic and high dose prednisone, the need for medications that have a steroid-sparing effect in the DM population is evident
 - These data support the urgency to develop medications that have a potential steroid-sparing effect to reduce the number of patients who could experience harmful steroid-related side effects
- Future analyses should evaluate the incidence of corticosteroid-related adverse events and the limitations of currently used corticosteroid-sparing medications in the DM population