EPH12

A Retrospective Natural History Study of Incident Adult Dermatomyositis and Polymyositis Patients Using Real World Data

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Background

- Idiopathic inflammatory myopathies (IIMs) are a group of rare, heterogeneous autoimmune disorders characterized by muscle inflammation and weakness. Extra-muscular manifestations affecting the skin, lungs, heart, gut, and joints are common, and mortality rates are increased[1-4].
- Dermatomyositis (DM) and polymyositis (PM) are the two main IIM subtypes. The Food and Drug Administration (FDA) and European Medicines Agency (EMA) have approved only one drug to treat IIM, but only adult DM patients[3].
- Gaps exist in understanding DM and PM patient demographic and clinical characteristics, treatment patterns, and extra-muscular disease progression rates, including occurrence of malignancies.

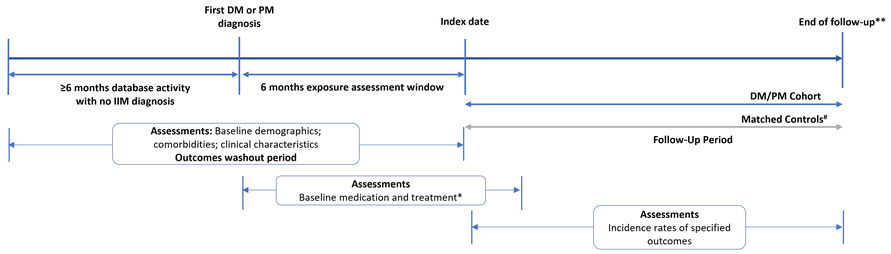
Objective

Among incident DM and PM patients, to describe baseline demographics, clinical characteristics, comorbidities, and treatments, and to compare incidence rates (IRs) of disease outcomes with those in matched controls (MCs).

Methods

- Data from incident adult (≥18 years) DM and PM patients were collected retrospectively from the US Optum Market Clarity database, including electronic health records (EHR) and claims data (study period: 01 January 2016–31 March 2021).
- Patients were required to have ≥6 months of database activity with no IIM diagnoses prior to their first IIM diagnosis during the study period and 6 months of database activity after their first IIM diagnosis during the study period (the latter 6-month period was the 'exposure assessment window' (EAW) (Figure 1).
- Patients were assigned to the IIM cohort (DM or PM) for which they had the greatest number of diagnoses during the EAW, with twice the weight given to inpatient diagnoses.
- The index date was defined as the day after the end of the EAW.
- The cohort of MCs (with no diagnosis of DM/PM) was matched to DM or PM patients based on age, sex, and index month/year.
- DM and PM cohorts and their MCs were followed up from the index date until either death, end of database activity, a post-index diagnosis of DM or PM other than the cohort-defining diagnosis or any DM or PM diagnosis for MCs, or end of the study period, whichever occurred first. Follow-up for an incident event ended at its first occurrence.
- Patients having an assessed outcome during the 12 months prior to their index date were not eligible for that outcome during follow-up.

Figure 1. Study Design



*Baseline medication and treatment were assessed during a 7-month period: the exposure assessment window plus one month; **Follow-up ended at either death, end of database activity, a post-index diagnosis of DM or PM other than the cohort-defining diagnosis or any DM or PM diagnosis for MCs, or end of the study period, whichever occurred first. Follow-up for an incident event ended at its first occurrence; #comparison groups of MCs (with no diagnosis of DM/PM) was matched to DM or PM patients based on age, sex, and index month/year.

DM, dermatomyositis; IIM, idiopathic inflammatory myopathies; PM, polymyositis

Results

1. Baseline Characteristics

A. Demographics

4,275 patients were enrolled in the DM cohort and 4,559 in the PM cohort. The mean age at index date was 54.5 in the DM cohort and 57.3 in the PM cohort. Both indications were more prevalent in females (Table 1).

B. Comorbidities and Clinical Characteristics

In both cohorts, the three most prevalent comorbidities were hypertension, hyperlipidemia, and gastroesophageal reflux disease (GERD; Table 2) and Raynaud's phenomenon was the most prevalent clinical characteristic, followed by arthritis and periungual erythema (Table 2).

C. Medication and Treatment

In both cohorts, systemic steroids were the most frequently prescribed medication and biologics the least (Figure 2).

2. IRs of Outcomes

IRs were higher for all outcomes, including all-cause death, in the DM and PM cohorts compared to their MCs. In DM cohort, GERD, cardiac dysrhythmia, and dysphagia had, respectively, the three highest IRs. In PM cohort, GERD, cardiac dysrhythmia, and ischemic heart disease had, respectively, the three highest IRs (Figure 3).

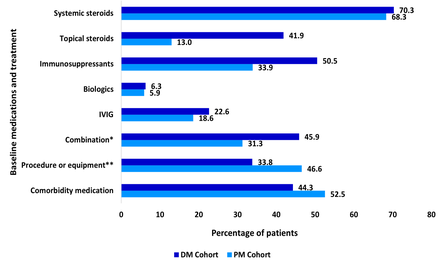
Table 1. Demographic Characteristics by Cohort

Demographic Characteristics*	Cohorts	
	DM (N=4,275)	PM (N=4,559)
Age, mean (SD)	54.5 (15.5)	57.3 (15.5)
Sex, n (%)		
Female	3,253 (76.1)	2,849 (62.5)
Male	1,022 (23.9)	1,710 (37.5)
Race, n (%)		
Asian	83 (1.9)	72 (1.6)
Black	429 (10.0)	856 (18.8)
Caucasian	2,928 (68.5)	2,692 (59.1)
Unknown	835 (19.5)	939 (20.6)
Ethnicity, n (%)		
Hispanic	245 (5.7)	244 (5.4)
Non-Hispanic	2,983 (69.8)	3,072 (67.4)
Unknown	1,047 (24.5)	1,243 (27.3)

*Assessed during the 12-month period prior to the index date

DM, dermatomyositis; PM, polymyositis; SD, standard deviation

Figure 2. Baseline Medication and Treatment by Cohort



*Combination: combination topical or systemic steroids + immunosuppressive or biologic; **Procedure or equipment: physical therapy, heat therapy (microwave or ultrasound), orthotics

DM, dermatomyositis; IVIG, intravenous immunoglobulin; PM, polymyositis

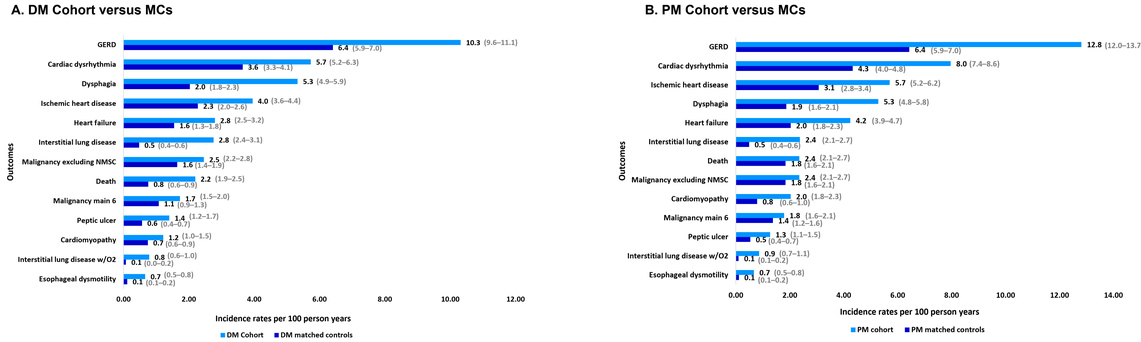
Table 2. Baseline Comorbidities (≥10% Prevalence) and Clinical Characteristics by Cohort

	Cohorts	
	DM (N=4,275)	PM (N=4,559)
Baseline Comorbidities*, n (%)		
Asthma	634 (14.8)	714 (15.7)
ILD	697 (16.3)	715 (15.7)
O^2 supplementation	532 (12.4)	824 (18.1)
Diabetes	1,116 (26.1)	1,541 (33.8)
Hyperlipidemia	1,721 (40.3)	2,337 (51.3)
Hypertension	2,152 (50.3)	2,914 (63.9)
Heart failure	450 (10.5)	799 (17.5)
Cardiac dysrhythmia	722 (16.9)	1,120 (24.6)
Ischemic heart disease	671 (15.7)	1,050 (23.0)
Malignancy, excluding NMSC	779 (18.2)	811 (17.8)
CKD	807 (18.9)	1,182 (25.9)
Liver disease	778 (18.2)	984 (21.6)
Dysphagia	837 (19.6)	821 (18.0)
GERD	1,331 (31.1)	1,575 (34.6)
Clinical Characteristics*, n (%)		
Gottron's papules	88 (2.1)	4 (0.1)
Periungual erythema	147 (3.4)	43 (0.9)
Raynaud's phenomenon	367 (8.6)	361 (7.9)
Alopecia areata	26 (0.6)	8 (0.2)
Cicatricial alopecia	22 (0.5)	9 (0.2)
Arthritis	206 (4.8)	251 (5.5)
Antisynthetase syndrome	1 (0.0)	2 (0.0)
Calcinosis	34 (0.8)	7 (0.2)
Ulceration	31 (0.7)	28 (0.6)

*Assessed during the 12-month period prior to the index date

CKD, chronic kidney disease; DM, dermatomyositis; GERD, gastroesophageal reflux disease; ILD, interstitial lung disease; NMSC, non-melanoma skin cancer; O^2, oxygen; PM, polymyositis

Figure 3. Incidence Rates and 95% Confidence Intervals Per 100 Person Years of Selected Outcomes: DM and PM Cohorts Versus Matched Controls



Main 6 malignancies: ovarian, lung, pancreatic, stomach, colorectal, basal or squamous cell

DM, dermatomyositis; GERD, gastroesophageal reflux disease; MCs, matched controls; NMSC, non-melanoma skin cancer; O^2, oxygen; PM, polymyositis

CONCLUSIONS

- In incident DM and PM patients, Raynaud's phenomenon was the most prevalent baseline clinical characteristic (although with <10% prevalence) of those assessed, systemic steroids were the modal baseline treatment, and GERD, cardiac dysrhythmia, dysphagia, and ischemic heart disease had the highest IRs of the outcomes assessed. DM and PM patients had higher IRs than MCs for all outcomes assessed, including all-cause death
- This real-world study addresses existing knowledge gaps in the epidemiology of incident DM and PM in the US, particularly the incidence rates of multiple extra-muscular disease manifestations. When compared with MCs, DM and PM patients had higher IRs of these manifestations, pointing to the need for improved treatment
- **Study Limitations:** Potential misclassification of diagnostic groups, baseline characteristics, and outcomes due to miscoding in the clinical setting, use of non-validated classification algorithms, and misclassification of non-incident cases and outcomes as incident due to insufficient look-back periods

References: 1. D'Silva, K. M. *et al. Rheumatology* **60**, 2653-2660 (2021) 2. Li, L. *et al. Seminars in Arthritis and Rheumatism* **50**, 834-839 (2020) 3. Neves, A., *et al*. *Rheumatology* **00,** 0-10 (2024) 4. Yang, X. *et al*. *Clinical Rheumatology* **39**, 1569-1579 (2020)

Author contributions: All authors contributed to the data acquisition, and the development, critical review, and final approval of this poster.
Disclosures: David M. Barnes and Stephen E. Schachterle are employees and stockholders of Pfizer, Inc. Thomas Edwards has no conflicts of interest or financial disclosures to declare.
Funding: This study and medical writing support were sponsored by Pfizer Inc.

Acknowledgements: Under the direction of the authors, Kanchan Bhati (M.Pharm; employee of Pfizer) provided medical writing support. Kripa Madnani (Ph.D., CMPP™) and Priyanka Jaisar (PhD), both employees of Pfizer, provided editorial support.