EXTENDED REPORT

Prevalence and clinical characteristics of adult polymyositis and dermatomyositis; data from a large and unselected Norwegian cohort

Cecilie Dobloug, Torhild Garen, Helle Bitter, Johan Stjärne, Guri Stenseth, Lars Grøvle, Marthe Sem, Jan Tore Gran, Øyvind Molberg

ABSTRACT

Objectives The occurrence of polymyositis (PM) and dermatomyositis (DM) in the general population is largely unknown and unbiased data on clinical and laboratory features in PM/DM are missing. Here, we aim to identify and characterise every PM/DM patient living in southeast Norway (denominator population 2.64 million), 2003–2012.

Method Due to the structure of the Norwegian health system, all patients with PM/DM are followed at public hospitals. Hence, all public hospital databases in southeast Norway were screened for patients having ICD-10 codes compatible with myositis. Manual chart review was then performed to identify all cases meeting the Peter & Bohan and/or Targoff classification criteria for PM/DM.

Results The ICD-10 search identified 3160 potential myositis patients, but only 208/3160 patients met the Peter & Bohan criteria and 230 the Targoff criteria (100 PM, 130 DM). With 56 deaths during the observation period, point prevalence of PM/DM was calculated to 8.7/100 000. Estimated annual incidences ranged from 6 to 1/1 000 000, with peak incidences at 50–59 (DM) and 60–69 years (PM). Myositis specific antibodies (Jo-1, PL-7, PL-12, signal recognition particle (SRP) and Mi-2) were present in 53% (109/204), while 137/163 (84%) had pathological muscle MRI. Frequent clinical features included myalgia (75%), arthritis (41%), dysphagia (58%) and dyspnoea (62%). Positive anti-Jo-1, present in 39% of DM and 22% of PM cases, was associated with dysphagia, arthritis and mechanic hands.

Conclusions Our data indicate that the population prevalence of PM/DM in Caucasians is quite low, but underscores the complexity and severity of the disorders.

INTRODUCTION

The idiopathic inflammatory myopathies (IIM) include three clinical syndromes; polymyositis (PM), dermatomyositis (DM) and sporadic inclusion body myositis (sIBM). PM and DM are systemic, inflammatory disorders, while sIBM appears to be a primary degenerative condition. In the current study, we focus only on PM and DM.

PM and DM are characterised by symmetrical weakness of proximal muscle groups. Additionally, patients with DM have a distinct rash. Inflammation in other organ systems are frequent in PM and DM; with interstitial lung disease as a major cause of mortality. Cancer is also a major clinical problem, particularly in DM. Autoantibodies are common in PM and DM, and more than 10 different, mutually exclusive myositis-specific antibodies (MSA) have been described. Interestingly, the MSA are associated with distinct clinical syndromes that often cross the classical distinction between PM and DM.

The Peter & Bohan diagnostic criteria from 1975 is still the gold standard when it comes to classifying PM and DM cases for research purposes. These criteria include key clinical features (muscle weakness and DM rash) and laboratory parameters (serum level of muscle enzymes, electromyography (EMG) and muscle histology), but not MSA or MRI of muscle tissue. Revised classification criteria, building on the Peter & Bohan criteria, with inclusion of MSA and MRI were proposed by Targoff et al in 1997. Other classification criteria have also been suggested. More recently, larger-scale consensus efforts have been undertaken by the International Myositis Classification Criteria Project (IMCCP). Interestingly, preliminary data from IMCCP presented at the EULAR-meeting in 2013, indicated that the Targoff criteria show the best sensitivity and specificity of established criteria.

Data on the epidemiology of PM/DM are limited, probably due to the rarity of the diseases, heterogeneous study populations and difficulties with classification. To our knowledge, there is only one population-based study on DM, with 29 cases defined solely by clinical features, and some few retrospective studies based on chart reviewing. The largest of these chart review studies, performed in the Allegheny County in Pennsylvania from 1963–1982, used predefined clinical criteria for case assignment, and identified 177 PM/DM cases. Interestingly, the study reported that the PM/DM incidence tripled during the study period. Few studies have been undertaken in Europe, but an annual incidence of 7.6 cases/million was estimated in a Swedish study with 21 PM/DM cases. Prevalence data for PM and DM vary from 5/100 000 to 21.5/100 000 depending on methods used for obtaining data, highest estimations done by calculated medical administrative data in the USA and Canada.

Overall, there appears to be large knowledge gaps on the epidemiology of myositis; little is known about the occurrence of PM/DM in the general population, and unbiased data on the frequencies of key clinical and laboratory features are largely missing. Hence, the aims of this study were...
Clinical and epidemiological research

to estimate the point prevalence of PM/DM in a defined area of Norway, with a denominator population of 2.64 million, and describe clinical characteristics and the frequencies of MSA in the resulting large and unselected cohort.

MATERIALS AND METHODS

Study cohort and denominator population

Southeast Norway consist of 10 counties with 2,642,246 inhabitants (by 31 Dec 2012) and includes the largest cities in Norway. There are 10 hospitals in southeast Norway; the largest is Oslo University Hospital (OUH), which is the primary local hospital for Oslo (with 600,000 inhabitants) and referral hospital for all the 10 counties in the region. In Norway, patients with connective tissue diseases, including PM/DM are followed by specialists, mostly rheumatologists, but in some cases also neurologists, based at public hospitals. Since 1999, all patients contacts in the specialist health service were electronically registered by 10th revised version of the International Classification of Disease (ICD-10) codes. The PM/DM cohort was selected from this denominator population and consisted of every person who fulfilled the study inclusion criteria for PM/DM (see below).

Study inclusion criteria

Patients were included if they fulfilled the following criteria: (A) disease classifiable as probable or definite adult PM or DM by the Peter & Bohan criteria and/or the Targoff criteria.9 10 To be classified as DM, a clinical rash compatible with DM (Gottron's sign or papules and/or Heliotrope rash) was required; (B) age above 18 years at disease onset; (C) registered in the Norwegian Central Register with a home address in southeast Norway between 1 January 2003 and 31 December 2012; (D) myositis not explained by the presence of another connective tissue disease (ie, Systemic lupus erythematosus, systemic sclerosis or mixed connective tissue disease).

Case-finding strategy

Sequential, partly overlapping acquisition routes for identifying all the adult PM/DM patients in southeast Norway in the period from 2003 to 2012 were used. First, broad searches across all the patient administrative databases of OUH, using the following ICD-10 codes: M33.1 (Dermatomyositis), M33.2 (Polymyositis), M33.9 (unspecified PM/DM), M60.1 (Interstitial myositis), M60.8 (Specified myositis), M60.9 (unspecified myositis), G72.4 (Inflammatory myopathy, not classified elsewhere), G72.8 (Other specified myopathies), G72.9 (Unspecified myopathy), G73.7 (Myopathy associated with disease classified elsewhere) were performed. All the patients who had received 1 of the 10 the ICD-10 codes above between 2003 and 2012 were then manually chart-reviewed by the principal investigator (CD) to identify patients meeting the study inclusion criteria. The records of every patient who fulfilled the criteria were independently re-examined (OM). The results of the OUH search showed that 99% of the patients classifiable as PM/DM were ICD-10 coded as M33 and/or M60. The majority of the excluded patients had ICD-10 codes from the G-chapter (neurology), with G72.9 as the most commonly used. Hence, the search through the administrative databases at the nine other hospitals in southeast Norway was limited to the six M33 and M60 codes. The charts of all the patients identified with M33 and/or M60 diagnoses were then manually reviewed. Data from the Norwegian Statistical Institute (Statistisk sentralbyrå- SSB, http://www.ssb.no) was used in calculation in point prevalence for each county in this health region. SSB contains updated geographical data for Norway.

Patient characteristics and disease measures

Predefined registration forms were used to record hospital chart data on the patients identified by the ICD-10-based case-finding strategy. Age, gender, time of symptom onset, time of disease onset (defined as the date when PM/DM was first diagnosed) and patient observation period was recorded. The observation period was terminated on 31 December 2012 or at the time of death. Disease duration was defined as the time from diagnosis to the end of the observation period. Targoff criteria were scored as positive by the following rules: (A) EMG/neurography described as myopathy by neurophysiologist; (B) muscle biopsy described by pathologist as compatible with inflammatory myopathy (excluding IBM). Pathology features consistent with DM were; perimysial inflammatory infiltrates and perifascicular muscle atrophy, whereas PM was identified by endomysial inflammatory infiltrates, invasion of healthy muscle fibres and ubiquitous MHC-1 expression; (C) positive MSA (anti-Jo-1, anti-PL-7, anti-PL-12, anti-signal recognition particle (SRP) and anti-Mi-2) by immune blotting or ELISA; (D) MRI findings compatible with myositis, as described by a trained radiologist. Additionally, the following clinical and laboratory parameters were recorded at disease onset and cumulatively during follow-up; myalgia (scored as positive when a specialist reported it as a persistent complaint by the patient), calcinosis cutis, mechanic hands, arthritis (as defined by a rheumatologist), arthralgia, dysphagia, sicca symptoms, Raynaud phenomenon, cough, dyspnoea, remitting fever, ESR (erythrocyte sedimentation rate), antinuclear antibodies and anti-Sjögren Syndrome A autoantibody (anti-SSA).

Ethical aspects

The Regional Committee of Medical ethics in Southern Norway (REK sør), the Norwegian Ministry of Health (the Norwegian Patient Registry) and Privacy Policy Department at OUH, have approved this study with all aspects related to patient data recording and ethical aspects related to the handling of patient sensitive material.

Statistical analysis

Analyses were done with SPSS, V20/21. Descriptive statistics; continuous variables with normal distribution was presented as mean with SD and range. Categorical variables were presented as numbers and percentages. Differences between groups were calculated with Student t test (2-tailed, unpaired), for continuous, normally distributed variables, and analysis of variance (ANOVA) plot for non-parametric distribution. The χ² test was used for the comparison of independent groups of categorical data. Regression analysis was used to assess correlations between MSA and autoantibodies. Crude OR with 95% CI, were used to find associations between MSA and clinical symptoms.

RESULTS

PM and DM case-finding

In total, the hospital searches identified 3160 patients with ICD-10 codes potentially compatible with PM/DM between 2003 and 2012 (figure 1). Manual chart review showed that only 7.5% (194/2605) of the patients identified at OUH, and 6.5% (36/555) of the cases identified at the nine other hospitals, met the Targoff criteria for PM or DM. The 2930 other patients either had neuromuscular diseases, amyopathic DM, juvenile
onset DM, sIBM, overlap syndromes, other connective tissue diseases, or they were miscoded.

Of the 230 patients meeting the Targoff criteria, 130 had DM and 100 PM. The majority of the patients (175/230; 76%), scored at least 4/6 points and were classified as definite PM/DM (figure 1 and online supplementary table S1). The Peter & Bohan criteria were met by 208 of these 230 patients (90%), but the frequency of definite PM/DM cases was lower (124/208; 60%) with these criteria (figure 1).

**Patient population**

At diagnosis, the mean age of the PM patients was 56.0 years, higher than the mean 51.6 years in DM (table 1). Median ages at diagnosis were 57 years (range 18–82) in PM and 54 years (range 18–92) in DM. The female to male ratios were higher in DM (2.1:1) than in PM (1.6:1). Mean time from symptom debut to diagnosis did not differ between the groups, but diagnostic delay above 2 years was more frequent in PM (29%) than in DM (2.1:1) than in PM (1.6:1). Mean time from symptom debut to diagnosis did not differ between the groups, but diagnostic delay above 2 years was more frequent in PM (29%) than in DM (29%) (p=0.005) (table 1). Peak incidence of PM was 60% with these criteria (range 50–69 years), whereas, DM peaked in the age group of 50–59 years (figure 2A). Interestingly, when adjusted for population age, the peak incidences of PM and DM were skewed towards higher age groups (figure 2B).

The number of newly diagnosed PM/DM cases in the study area proved to be very stable from year to year across the period from 2003 to 2012 for the total number of patients, but the ratio between PM and DM cases was more variable (from 2003 to 2012 for the total number of patients, but the area proved to be very stable from year to year across the period skewed towards higher age groups (population age, the peak incidences of PM and DM were

**Point prevalence**

By 31 December 2012, 174 of the 230 PM/DM patients included were alive and living in the study area; giving a point prevalence of PM/DM in southeast Norway of 8.7/100 000 (95% CI 4.5 to 11.2) (figure 3). The highest point prevalence was observed in two of the smaller counties Telemark (population 170 902) and Vest-Agder (176 353) with 16.4/100 000 and 12.3/100 000, respectively (figure 3).

**Overview of the items assessed by the Targoff criteria**

Almost all patients had muscle weakness. Elevated CK was more often recorded in PM than in DM (92 vs 81%), (table 2), but the maximum CK levels did not differ between the groups (table 1). Muscle biopsy findings consistent with inflammatory myopathy were noted in 208 of the 230 patients (90%), but only 70% of the biopsies had definite PM or DM histology features (table 2). Pathological MRI findings were noted in 137/163 (84%) of the patients, while positive MSAs were identified in 59% of DM patients and 41% of PM patients (table 2 and online supplementary table S1).

**Clinical characteristics**

Chart information about clinical features at disease onset and during follow-up was recorded and cumulative frequencies estimated. Muscle weakness was present in 84% at disease onset and cumulatively in 97% (figure 4). Myalgia was also frequent, with a cumulative risk of 76%. Dysphagia was quite rare at disease onset (23%), but increased to 58% during follow-up. Dyspnoea was more frequent in DM than in PM, at disease onset (44% vs 22%, p=0.0005) and cumulatively (71% vs 51%, p=0.002) (figure 4). Raynaud’s phenomenon and mechanic hands were also more prominent in DM than in PM (39% vs 19%, p=0.009) and (39% vs 3% p=0.00001) respectively.

**Myositis-specific antibodies**

The most commonly tested and detected MSA was anti-Jo-1, being present in 45/204 (22%) of the patients, 47/121 (39%) in DM and 18/83 (22%) in PM (table 2). Anti-Jo-1 was associated with anti-SSA (p=0.031). Data coverage on the other MSA included were alive and living in the study area; giving a point prevalence of PM/DM in southeast Norway of 8.7/100 000 (95% CI 4.5 to 11.2) (figure 3). The highest point prevalence was observed in two of the smaller counties Telemark (population 170 902) and Vest-Agder (176 353) with 16.4/100 000 and 12.3/100 000, respectively (figure 3).

**Table 1** Demographics and key laboratory data on the polymyositis (PM) and dermatomyositis (DM) study cohort

<table>
<thead>
<tr>
<th>Total (n=230)</th>
<th>PM (n=100)</th>
<th>DM (n=130)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, n (%)</td>
<td>150</td>
<td>62 (62)</td>
<td>88 (68)</td>
</tr>
<tr>
<td>Age at diagnosis (yrs, mean (SD))</td>
<td>53.5</td>
<td>56.0 (14.9)</td>
<td>51.6 (15.19)</td>
</tr>
<tr>
<td>Disease duration (yrs, mean (SD))</td>
<td>7.7</td>
<td>8.8 (7.7)</td>
<td>6.9 (8.3)</td>
</tr>
<tr>
<td>Diagnostic delay* &gt;2 years, n (%)</td>
<td>43 (20)</td>
<td>29 (29)</td>
<td>18 (14)</td>
</tr>
<tr>
<td>Maximum CK† (UL), mean (range)</td>
<td>4165</td>
<td>3902 (95–30348)</td>
<td>4397 (74–39000)</td>
</tr>
<tr>
<td>ESR‡ (mm) at debut, mean (range)</td>
<td>42</td>
<td>39 (2–105)</td>
<td>44 (6–100)</td>
</tr>
<tr>
<td>Deceased, n (%)</td>
<td>56</td>
<td>30 (30)</td>
<td>26 (20)</td>
</tr>
</tbody>
</table>

Continuous variables are presented as mean with range. Categorical variables are presented as numbers and percentages (%).

*Diagnostic delay: the time period from first onset of symptoms to diagnosis.
†CK: Upper reference values; 210 U/L in females, 400 U/L in males 0–49 years and 280 U/L in males >50 years.
‡ESR in mm. Upper reference values; 20 mm in females 0–49 years, 25 mm in females >50 years, 15 mm in males 0–49 years and 20 mm in males >50.
CK, creatine kinase; ESR, erythrocyte sedimentation rate.
156 and anti-SRP in 13/157 (table 2). Ten PM/DM patients tested positive for two or more MSAs (data not shown). Anti-SRP was more frequent in PM than in DM (table 2). Correlation analyses were restricted to anti-Jo-1 and showed correlations between anti-Jo-1 and the following clinical features; dyspnoea, arthritis and mechanic hands. Unadjusted OR arthritis 7.5 (CI 95% 3.9 to 14.6), OR dyspnoea 7.7 (CI 95% 3.5 to 16.9) and OR mechanic hands 4.5 (CI 95% 2.3 to 8.7).

DISCUSSION

Population-based data on prevalence and clinical characteristics of PM/DM are very limited. Here, we aimed to fill this knowledge gap by assessing all the PM/DM patients living in a region of Norway during a defined time period. The study design was tailored to the structure of the Norwegian Health System and, although not fully population based, we do not find it likely that we missed many PM/DM cases. Hence, we believe the observed point prevalence of 8.7/100 000 is a close approximate of the true population prevalence of PM/DM in southeast Norway.

There are important differences between the current study and previous PM/DM epidemiology reports. First, we applied a wide range of relevant ICD-10 codes, over a long acquisition period, to ensure that all the PM/DM cases living in the study area were captured. In the previous studies, cases were captured by clinical characteristics alone,16 ICD-9 codes18 or a positive muscle biopsy.23 Second, we used updated classification criteria, by Targoff to encompass MRI and MSA. With these criteria, the overall number of classifiable patients increased only by 10% compared to the Peter & Bohan criteria, but the frequency of definite cases raised by 30%. Third, we focused on point prevalence data, while previous studies mostly presented retrospective estimates of annual incidences. For comparative purposes, we also did an estimate of annual incidence and found that it ranged between 6/ and 10/1 000 000. Our incidence estimates were higher than in the early, chart review-based studies,17–19 but lower than the ones estimated from recent database searches in the USA and Canada.26–28 Notably, the recent database studies were solely based on code-searches; which may capture non-myositis cases and overestimate frequencies. In our case, depending on code searches alone would have increased the number of PM/DM cases dramatically.

Interestingly, the observed PM/DM prevalence differed from 6.4 to 16.4/100 000 in the counties of the study area. We do not know the reason why, but think that varying density of rheumatologists across the counties may be a contributing factor. A more speculative hypothesis is that environmental factors may be involved; Telemark, the county with the highest prevalence is also the most heavily industrialised area in southeast Norway.

We believe that the current study has major strengths. Since it was performed in an area with a denominator population of 2.6 million, it produced a large-sized, unselected PM/DM cohort. More importantly, however, was the use of multiple data-acquisition routes to obtain cohort completeness.
Reassuringly, intermediary analyses showed that almost all the PM/DM patients in the study cohort were captured more than once, either at more than one site (ie, locally and at the OUH referral centre) and/or at more than one time point during the study period. Finally, the frequency of missing data in the cohort, with the possible exception of non-Jo-1 MSA, was also very low.

A limitation of this study was that the acquisition of clinical information and data was based on retrospective review of medical records, with missing and lacking documentation. We did, however, find that the number of potential PM/DM cases rejected due to missing information was low (less than 10 cases), indicating that the magnitude of this problem was not large. Another potential weakness was selection bias. All the charts at OUH, and the incoming registration forms from the local hospitals, were reviewed by the study principal investigator (CD) alone, but biased judgment was tried to overcome by discussion with coauthors on a case-to-case notion. There are limitations related to the use of the Targoff criteria. Early PM cases may be missed out because they do not fulfill the criteria and the requirement for many tests to be performed increases the risk of underestimation due to missing data.

Interestingly, the DM to PM ratio, the female to male ratios, and the overall frequencies of important clinical features like dyspnoea, arthralgia, Raynaud and Mechanic hands reported in the current study are in accordance with (pooled) data from singlecentre and multicentre cohorts.\(^1\)\(^3\)\(^6\)\(^1\)\(^2\)\(^9\)\(^3\)^1\(^2\)\(^3\)\(^1\)^1\(^9\)\(^2\)\(^2\)\(^3\)\(^3\)\(^1\)\(^4\)\(^5\) This possibly reflects that centre-based cohorts often include the majority of PM/DM cases in their respective geographical areas. Some differences were noted. Anti-Jo1 was identified in 28% of the PM/DM patients, and this was higher than the 18–25% reported in large case series.\(^6\)\(^3\)\(^2\)\(^3\)\(^1\)^1\(^9\)\(^2\)\(^2\)\(^3\)\(^3\)\(^1\)\(^4\)\(^5\) Anti-Jo-1 was strongly associated with dyspnoea, arthritis and mechanic hands; supporting the concept of the antisynthetase syndrome as a clinical entity. Notably, contrary to most previous studies, we found that Jo-1 was more common in DM than in PM.

In conclusion, this study provides novel data on the prevalence and clinical characteristics of PM and DM in a Caucasian population. We believe this study to be robust and that it serves as an important contribute to the surveillance of PM and DM in Europe. We hope in the future to follow this unique PM/DM cohort and perform further studies to get valuable insight into these complex illnesses.

### Acknowledgements
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#### Table 2
Frequencies of positive Targoff PM/DM criteria items and myositis specific autoantibodies in polymyositis (PM) and dermatomyositis (DM) study cohort

<table>
<thead>
<tr>
<th>Targoff items; n/N (%)</th>
<th>Total (n=230)</th>
<th>PM (n=100)</th>
<th>DM (n=130)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal muscle weakness;</td>
<td>224/230 (97)</td>
<td>99/100 (99)</td>
<td>125/130 (96)</td>
<td>0.21</td>
</tr>
<tr>
<td>Pathological CK</td>
<td>196/230 (85)</td>
<td>92/100 (92)</td>
<td>105/130 (81)</td>
<td>0.016</td>
</tr>
<tr>
<td>Pathological electromyography</td>
<td>131/158 (83)</td>
<td>70/82(85)</td>
<td>61/76(80)</td>
<td>0.41</td>
</tr>
<tr>
<td>Positive muscle biopsy*</td>
<td>208/230 (90)</td>
<td>96/100 (96)</td>
<td>112/130 (86)</td>
<td>0.98</td>
</tr>
<tr>
<td>DM rash†</td>
<td>123/223 (55)</td>
<td>0 (0)</td>
<td>123/130 (95)</td>
<td>0.000</td>
</tr>
<tr>
<td>Pathological MRI findings</td>
<td>137/163 (84)</td>
<td>54/62(87)</td>
<td>83/101(82)</td>
<td>0.19</td>
</tr>
<tr>
<td>Myositis specific antibodies</td>
<td>109/204 (53)</td>
<td>39/83 (47)</td>
<td>70/121 (58)</td>
<td>0.19</td>
</tr>
<tr>
<td>Jo-1</td>
<td>65/204 (28)</td>
<td>18/83(22)</td>
<td>47/121 (39)</td>
<td>0.009</td>
</tr>
<tr>
<td>PL-12</td>
<td>16/158 (10)</td>
<td>7/63</td>
<td>9/95</td>
<td>0.45</td>
</tr>
<tr>
<td>PL-7</td>
<td>10/156 (6)</td>
<td>4/61</td>
<td>6/95</td>
<td>0.40</td>
</tr>
<tr>
<td>SRP</td>
<td>13/156 (8)</td>
<td>10/60</td>
<td>3/96</td>
<td>0.023</td>
</tr>
<tr>
<td>Mi-2</td>
<td>10/157 (6)</td>
<td>3/61</td>
<td>7/96</td>
<td>0.93</td>
</tr>
<tr>
<td>Antinuclear antibodies</td>
<td>120/216 (52)</td>
<td>37/92 (40)</td>
<td>83/124 (67)</td>
<td>0.000</td>
</tr>
<tr>
<td>Anti-SSA antibodies</td>
<td>65/195 (28)</td>
<td>17/82 (24)</td>
<td>46/117 (39)</td>
<td>0.031</td>
</tr>
</tbody>
</table>

*Findings consistent with myositis were recorded in 96 PM patients, but only 67/96 (70%) had definite PM histology features. Likewise, typical DM histology features was noted in 78/112 (70%) of the DM patients with biopsy confirmed myositis.

†DM rash was mentioned, but incompletely described, in the medical journals of seven patients. These patients were classified as DM because they also had typical DM histology. ANA, antinuclear antibodies; anti-SSA, anti-Sjøgren Syndrom A autoantibody; SRP, signal recognition particle.

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#### Figure 4
Accumulated frequencies of clinical characteristics during the disease courses of the polymyositis (PM) and dermatomyositis (DM) patients in the study cohort.
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