ORIGINAL ARTICLE

US Incidence of Juvenile Dermatomyositis, 1995–1998: Results From the National Institute of Arthritis and Musculoskeletal and Skin Diseases Registry

EDUARDO P. MENDEZ,[1] REBECCA LIPTON,[2] ROSALIND RAMSEY-GOLDMAN,[3] PHIL ROETTCHER,[4] SUSAN BOWYER,[4] ALAN DYER,[3] AND LAUREN M. PACHMAN,[5] FOR THE NIAMS JUVENILE DM REGISTRY PHYSICIAN REFERRAL GROUP

Objective. To estimate the incidence of juvenile dermatomyositis (juvenile DM) in the United States between 1995 and 1998.

Methods. Physician referrals to the National Institute of Arthritis and Musculoskeletal and Skin Diseases Juvenile Dermatomyositis Research Registry and the National Pediatric Rheumatology Disease Registry from Indiana University were utilized for a 2-source capture-recapture estimation of Juvenile DM annual incidence.

Results. For children 2–17 years of age, the estimated annual incidence rates from 1995 to 1998 in the US ranged from 2.5 to 4.1 juvenile DM cases per million children, and the 4-year average annual rate was 3.2 per million children (95% confidence interval 2.9–3.4). Estimated annual incidence rates by race were 3.4 for white non-Hispanics, 3.3 for African American non-Hispanics, and 2.7 for Hispanics. During the 4-year period of the study, completeness of ascertainment for the combined registries ranged from 56% to 86% and girls were affected more than boys (ratio 2.3:1).

Conclusion. This study provides evidence for sex, and possibly racial differences in the risk of juvenile DM in the US.

KEY WORDS. Juvenile dermatomyositis; Incidence; Registry; Capture-recapture; Epidemiology.

INTRODUCTION

Juvenile dermatomyositis (juvenile DM) is a rare pediatric vasculopathy, and yet the most common inflammatory myopathy of childhood. It is characterized clinically by progressive weakness (primarily in the proximal muscles of the upper and lower extremities) and a rash found predominantly on the face and extremities (1,2). Children are diagnosed with juvenile DM when a combination of symmetrical muscle weakness, erythematous skin changes, and any of the following diagnostic test results are positive: muscle biopsy with evidence of inflammatory myositic changes, elevated muscle enzymes (creatine kinase, aldolase, lactic acid dehydrogenase, and serum glutamic oxalotransaminase), and observation of electromyographic patterns typical of myositis (3). Confidence in the diagnosis of juvenile DM is based on the number of these diagnostic criteria fulfilled.

Because juvenile DM is a rare disorder, its epidemiologic features have not been well characterized and it is therefore difficult to estimate secular changes in incidence. Published juvenile DM incidence rates have ranged from 1.9 to 4.2 cases per million children (4–6). It is possible that these estimates were inaccurate because they were based on extrapolations from referral center patient lists. The existing national disease surveillance systems consist of data retrieved from multiple sources to aid in rapid detection of epidemics. Other ongoing passive surveillance systems include a variety of national voluntary

reporting systems (e.g., recreational injury) that have informants submit data to a central database (7). Noncommunicable disease surveillance efforts, utilizing disease-specific population-based registries, are often limited to specific geographic areas (such as a county). All of these surveillance systems consume large amounts of resources and are therefore reserved for diseases that are communicable (i.e., tuberculosis, or autoimmune deficiency syndrome), common (i.e., cancer, diabetes, or coronary heart disease), or that have generated substantial public support and funds (i.e., sports and recreation injuries). These resources have not been applied to rare diseases such as juvenile DM.

The current study was designed to meet one of the specific aims of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) Juvenile Dermatomyositis Research Registry, which was to estimate the annual incidence of juvenile DM in the US as accurately as possible. This was the first opportunity in the US to examine multiple valid sources of national ascertainment and to utilize them for refining incidence calculations for juvenile DM. We used the NIAMS Juvenile Dermatomyositis Research Registry and the Pediatric Rheumatology Disease Registry (PRDR) in a 2-source capture-recapture analysis (8) to estimate the annual incidence of juvenile DM overall and by race for the US from 1995 to 1998. These 2 registries were collecting cases during a similar time frame, were capturing juvenile DM cases across the US, and were able to provide data that were easily retrievable for the 2-source comparison.

PARTICIPANTS AND METHODS

Patient ascertainment. The NIAMS Juvenile Dermatomyositis Research Registry was established to identify incident cases of juvenile DM diagnosed by physicians between 1994 and 1999 in the US. Individual physician letters, journal advertisements, and national announcements at rheumatology conferences were used to publicize the NIAMS registry to all US pediatric and adult rheumatologists listed in the American College of Rheumatology directory on an annual basis. In addition, the NIAMS JDM Registry study advertisement was sent to the nation's pediatric neurologists and dermatologists as listed in their respective professional organizations' national membership directories. A large proportion of the physician-diagnosed juvenile DM referrals were initially received via a toll-free "hot-line." Registry forms were distributed to potential referring physicians by mail, fax, and E-mail, as well as the via the website URL: http://www.childrensmemorial.org/jdm. Only the data for date of diagnosis, race, and sex were sufficiently complete to allow for valid estimations, thus age distributions were not examined.

The second independent referral source used for estimating JDM incidence was the national PRDR at Indiana University. This registry was designed to collect newly diagnosed cases of any pediatric rheumatic disease (pediatric rheumatology diagnoses) from 69 participating centers covering 33 states (plus Washington DC) reported

using the appropriate ICD-9 diagnosis codes (9). The ICD-9 diagnosis code for juvenile DM utilized on the PRDR referral form was 710.3. Juvenile DM was listed as one of the top 25 most frequently coded diagnoses submitted to the PRDR (10). The PRDR had been collecting information on initial patient visits to pediatric rheumatology clinics since 1992; while the NIAMS Registry obtained juvenile DM case referrals diagnosed exclusively between January 1994 and October 1999.

Case definition and inclusion-exclusion criteria for juvenile DM. Any child 2–17 years of age referred to either of the 2 registries who was diagnosed by a physician with JDM between January 1, 1995 and December 31, 1998 was eligible to be considered for inclusion in this study. For those lacking a diagnosis date in the referral data set, the assumption was made that the date of the first visit to the referring physician was the diagnosis date. For the NIAMS Registry, those who met the standard diagnostic criteria (3) were included, while those cases who were referred with evidence of muscle involvement but no observation of skin changes (erythema on face, hands, or knuckles, purplish eyelids, or nailfold capillary dropout) were not registered. Thirty-five percent of the referred cases lacked sufficient diagnostic criteria to meet the standard case-definition, but they had enough information to meet the presumptive case-definition for this study (rash and weakness). Each juvenile DM referral was crosschecked against previous registry lists to avoid duplication.

Inclusion in the PRDR was based on a physician's diagnosis, under the assumption that referring physicians for both registries were aware of published juvenile DM diagnostic criteria, and therefore were accurately diagnosing the syndrome. There were 461 NIAMS Registry referrals, of which 395 met the study inclusion criteria for the years 1995–1998 and were utilized for the incidence rate calculations. Of the total 531 juvenile DM cases collected by the PRDR between 1992 and 1998, 276 were eligible to be included in this analysis because they were diagnosed in the appropriate time span.

Informed consent. The capture–recapture process completed with the PRDR portion of the NIAMS Juvenile Dermatomyositis Research Registry study was exempt from Independent Review Board review because it qualified under the category of disease registries, and the data had only sufficient identifiers to allow for the matching of cases referred to the 2 registries.

Capture-recapture strategy and statistical methods. Capture-recapture is a simple method that is used to reduce the problems of under-ascertainment when multiple incomplete data sources are available (11) It requires ascertainment of cases from at least 2 independent data sources. The computations used in this study (Figure 1) have been developed and utilized for other diseases (e.g., cancer [12], diabetes [12–14], and multiple sclerosis [15]), and were used to calculate the estimated total number of cases for the years 1995–1998.
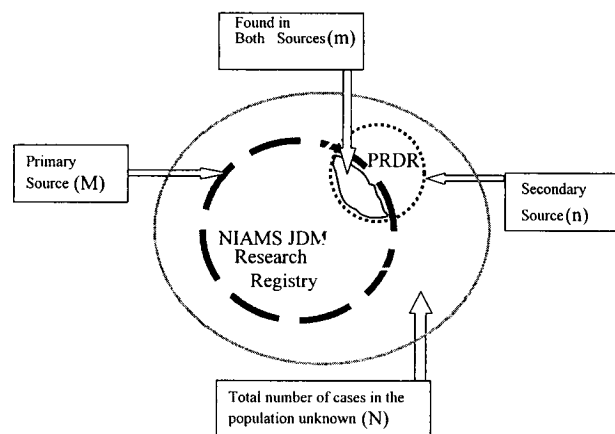
Figure 1. Capture-Recapture Methodology and Formulas utilizing 2 referral sources. $N = \{[(M+1)\ (n+1)\ /\ (m+1)]\ -1\}$ Var. $(N) = [(M+1)\ (n+1)(M-m)(n-m)]\ /\ (m+1)^2\ (m+2)$ 95% Confidence interval $= N \pm 1.96\ (Var.\ (N)^{1/2})$. PRDR = Pediatric Rheumatology Disease Registry; NIAMS = National Institute of Arthritis and Musculoskeletal and Skin Diseases; JDM = juvenile dermatomyositis.

Estimating race-specific incidence rates. To estimate the race-ethnic distribution of those without this information, we used the sum of capture-recapture estimates by race. We were able to calculate race-specific rates for the 3 major ethnic groups. The proportions from the known race distribution were applied to the additional estimated cases from the capture-recapture analysis. Estimated total race-specific rates were not computed for American Indian or Alaskan native or Asian /Pacific Islander since the numbers were very small.

Incidence rate calculations. Incidence rates and 95% confidence intervals (95% CIs) were calculated using age-specific 1995–1998 population projections from the United States Census (16). It was assumed that the estimated number of cases had a normal distribution in calculating the corresponding 95% CIs. The average annual 4-year national incidence rates were calculated by using the 1997 population projections for the denominator, since this was the mid-point year. The annual estimated incidence rates were compared between each pair of years using the rate and its estimated variance; P values less than 0.05 for these comparisons were considered statistically significant. No correction was made for multiple comparisons.

RESULTS

The NIAMSD Registry received referrals from 127 different referral centers and 46 US states (plus Washington, DC), while the PRDR received pediatric juvenile DM referrals from 39 medical centers and 30 US states (plus Washington, DC). The 2 registries had 31 medical centers in common. Referrals were contributed by 155 different physicians to the NIAMS Registry and 108 different physicians to the PRDR. There were 49 physicians who made referrals to both registries.

In the NIAMS Registry, there were 62 cases diagnosed between 1995 and 1998 lacking a clear diagnosis date; 7 cases were missing data on sex; and 30 cases were missing data on race. Data on sex were missing for 56 of 276 PRDR cases, race was missing for 64 cases, and specific dates of diagnosis were unavailable for 21 cases (7.6%).

The NIAMS Registry cases were obtained primarily from pediatric rheumatologists (87%), although other cases were identified by the collective efforts of adult rheumatologists (4.1%), neurologists (5.6%), dermatologists (0.9%), pediatricians (1.1%), and other subspecialists (0.9%). The race and sex distributions of the cases were white non-Hispanic (65.1%), Hispanic (14.2%), African American non-Hispanic (11.4%), Asian or Pacific Islander (1.3%), American Indian or Alaskan Native (0.5%), never clearly identified for race (7.6%), male (29.6%), female (68.6%), and never clearly identified for sex (1.8%) (Table 1).

Girls appeared more often than boys (ratio 2.3:1) in the NIAMS Registry database. The female-to-male ratio by race revealed the following: white non-Hispanic (2.4:1), African American non-Hispanic (1.8:1), Hispanic (1.9:1), Asian or Pacific Islander (4:1), American Indian or Alaskan Native (100% female), those lacking race identifiers (3.8:1) (Table 1).

Utilizing the referred cases collected by the 2 registries and the capture-recapture formulas (Figure 1), we calculated the annual point estimates and their respective 95% CIs for each year as follows: 1995, 251 (95% CI 191–311); 1996, 154 (95% CI 130–177); 1997, 173 (95% CI 155–191); 1998, 219 (95% CI 166–271). The point estimate for the

Table 1. Sex and ethnic distribution of 395 US juvenile DM referrals from the NIAMS Registry, 1995–1998*			
Ethnicity/Race	**No. female/ male (ratio)**	**Not clearly identified**	**Total cases**
White non-Hispanic	181/76 (2.4:1)	0	257
Hispanic	37/19 (1.9:1)	0	56
African American non-Hispanic	28/16 (1.8:1)	1	45
Asian or Pacific Islander	4/1 (4:1)	0	5
American Indian or Alaskan Native	2/0 NA	0	2
Not clearly identified	19/5 (3.8:1)	6	30
Total referrals	271/117 (2.3:1)	7	395

* DM = dermatomyositis; NIAMS = National Institute of Arthritis and Musculoskeletal and Skin Diseases; NA = not applicable.

Year	Cases found in PRDR	Cases found in NIAMS	Cases found in both sources	Capture-recapture point estimate (95% CI)	Population estimates (in millions)†	Incidence estimates per 1 million (95% CI)
1995	83	86	28	251 (191–311)	61.059	4.1 (3.1–5.1)
1996	65	88	37	154 (130–177)	61.738	2.5 (2.1–2.9)‡
1997	60	136	47	173 (155–191)	62.296	2.7 (2.5–3.0)§
1998	68	85	26	219 (166–271)	62.653	3.4 (2.6–4.3)
Average	276	395	138	788 (714–862)	62.296¶	3.2 (2.9–3.4)

Table 2. Juvenile dermatomyositis (2–17 years of age) incidence estimates in the US by year of diagnosis (1995–1998)*

* PRDR = Pediatric Rheumatology Disease Registry; NIAMS = National Institute of Arthritis and Musculoskeletal and Skin Diseases; 95% CI = 95% confidence interval.
† US population projections (2–17 years of age) (16).
‡ Significantly different from 1995 annual rate, $P < 0.01$ and 1998 annual rate, $P < 0.03$.
§ Significantly different from 1995 annual rate, $P < 0.01$.
¶ 1997 population estimate used to represent a mid-study time point.

4-year total was 788 (95% CI 714–862) (Table 2). Similarly, point estimates for the 3 major race-ethnic groups (white non-Hispanic, African American non-Hispanic, and Hispanic) were 417, 91, and 72, respectively (Table 3).

There were a total of 580 estimated cases for the 3 major race groups and 12 estimated cases that fell into the other 2 race groups (a total of 592). Thus, an additional 196 estimated cases lacked race-ethnicity and were assigned to specific groups based on the race-ethnicity distribution in the 592 estimated cases (138 white non-Hispanic, 30 African American non-Hispanic, 24 Hispanic, and 4 other races). The corresponding national average annual incidence estimates per 1 million children ages 2–17 years for the 3 major race groups were 3.4 white non-Hispanic, 3.3 African American non-Hispanic, and 2.7 Hispanic (Table 3). Because of the estimation procedure it was not possible to accurately calculate a 95% CI for each race group, nor test statistical differences between races.

The average estimated annual incidence rate for the US for the years 1995–1998 was 3.2 per million children 2–17 years of age, (95% CI 2.9–3.4) for all race-sex groups combined. Year-by-year estimated JDM incidence rates ranged from 2.5 (95% CI 2.1–2.9) in 1996 to 4.1 (95% CI 3.1–5.1) in 1995 (Table 2). The estimated annual rates for 1996 and 1997 differed significantly from the rate in 1995 ($P < 0.01$). The rate in 1996 was also significantly lower than the rate in 1998 ($P < 0.03$).

For each of the years 1995–1998, the completeness of ascertainment for the NIAMS Registry was 34%, 57%, 79%, and 39%, respectively, while the completeness of the PRDR was 33%, 42%, 35%, and 31%. The combined registries revealed an overall capture-completeness of 68%, and 56%, 75%, 86%, and 58% by year, respectively.

DISCUSSION

The present findings were similar or even slightly greater then those observed in previously published juvenile DM incidence studies, which may have been inaccurate because they were based on extrapolations from referral center case-series. One advantage of using both the PRDR and the NIAMS Registry was that these national registries were less likely to be subject to local and regional disease incidence variations. For example, one incidence study,

which accumulated 124 myositis-related cases, estimated the 1963 to 1968 average annual incidence in the state of Tennessee as 3.7 cases per million children 5–9 years of age, and 4.2 cases per million children 10–14 years of age (17). A study of polymyositis/dermatomyositis children in Allegheny County, Pennsylvania, suggested that from 1963 to 1982 the average annual incidence of juvenile DM was approximately 2.5 cases per million children under the age of 15 years (4). Researchers found similar annual incidence rates for children under the age of 15 living in Israel (5). A British study estimated the annual incidence of juvenile DM in the UK and Ireland as 1.9 cases per million children under the age of 16 years (6).

The current study is subject to several of the classic limitations of estimating incidence from disease registries. First, there is the potential for misclassification of disease status. However, since the majority (over 85%) of the juvenile DM cases were referred by pediatric rheumatologists, it is probable that they were correctly identified. There were a few referred cases that did not fit the Bohan and Peter diagnostic criteria (3) for myositis, and since some of the more expensive diagnostic tests (i.e., muscle biopsy or electromyogram) were not ordered by all physicians, it is possible that some of the referred cases were not truly juvenile DM. Furthermore, misclassification may occur, because juvenile DM may evolve into other pediatric rheumatologic conditions (such as overlap syndrome), and a few children may be diagnosed with other syndromes in which myositis is associated with a known serologic myositis-specific marker (18).

A second difficulty with these databases is variation in the amount of available clinical and demographic information (19). Data on sex and race ethnicity were unavailable for some individuals, and had to be inferred, although there is no a priori reason to believe that those who lacked this information differed in sex or ethnic distribution from those with complete data.

Perhaps the most important limitation of the current study is its relatively low ascertainment rate. Low ascertainment in monitoring the incidence of this rare disease may have resulted from a variety of circumstances in this study. First, the Indiana University PRDR was not intended (in itself) to calculate incidence rates, i.e., it was not established to achieve complete case ascertainment.

Table 3. Juvenile dermatomyositis (2–17 years of age) incidence estimates in the US by ethnic background (1995–1998)*

	Cases in PRDR	Cases in NIAMS	Cases in both	Initial capture-recapture point estimate	Additional cases estimated	Augmented point estimate for 4 years	Population estimate (millions)†	National total incidence for 4 years	National average annual incidence estimate (per 1 million)
n-Hispanic	169	257	104	417	138	555	41.044	13.5	3.4
	23	45	11	91	30	121	9.215	13.1	3.3
	17	56	13	72	24	96	8.971	10.7	2.7
	209	358	128	580	192	772‡	59.23	13.0	3.2

eumatology Disease Registry; NIAMS = National Institute of Arthritis and Musculoskeletal and Skin Diseases.
projections (2–17 years of age) utilized to represent a mid-study time point (16).
are American Indian/Alaskan Native or Asian/Pacific Islander.

Second, participation in the research required substantial physician and staff effort in order to forward the pertinent data. Accommodations were made by both registries to receive referrals by phone, fax. or E-mail, yet it was apparent that some health care centers contacted had not referred any or all of their juvenile DM cases. Finally, not all practitioners who may treat juvenile DM were contacted. It would be difficult to ascertain how many additional medical centers in the US could have referred juvenile DM cases, but did not, since the condition is diagnosed and treated by a variety of sub-specialists. Quite possibly, a number of less severe cases may have been treated by community practitioners who could have been unaware of the existence of either of the 2 registries.

The best year for the combined registries in capturing juvenile DM cases was 1997, when 149 of the estimated 173 cases (86%) were ascertained (Table 2). This may have been a result of a heightened awareness among practitioners, after publication and dissemination of articles describing the 2 registries (9,10). The slight annual increases in juvenile DM incidence estimated between 1996 and 1998, may have resulted from improvements in the NIAMS Registry recruitment and followup process or from more cases actually occurring. Since the rate of referral from the PRDR Registry was stable over time, it is possible that the NIAMS Registry annual variation in cases may have been a result of an artifact, rather than reflecting an environmental cycle.

Finally, it is likely that the NIAMS and PRDR registries were somewhat interdependent, since there was overlap in the pediatric rheumatologists making referrals to each registry. The failure of the critical assumption of independence for capture-recapture incidence calculations may have undermined these results. Unfortunately, the statistical assessment of the effect of dependency between referral sources, is limited to approaches utilizing 3 or more sources of case ascertainment (8,20). In a 2-source model, any estimate of missing cases is biased downward and cannot be quantified, therefore estimates usually represent a minimum (8,12–15).

Utilizing only the NIAMS JDM Registry data girls were diagnosed with juvenile DM approximately twice as often as boys (Table 1). The differences are relatively small and this comparison is problematic given the missing data on race and sex. Due to the small sample size, the female:male ratios for the American Indian/Alaskan Native and Asian/Pacific Islander children are not able to capture an accurate sex ratio difference. A 1990 study that pooled juvenile DM data from 9 published studies (114 cases) revealed a female:male ratio of 1.7:1 (21). Another study, published in 1995, reported a ratio of 5.0:1, which was documented as being much higher than that seen by other studies. In a Singapore study of children diagnosed with juvenile DM

while Hispanics may have a lower incidence of juvenile DM. Because of the combined effect of potential disease misclassification, missing data, and low case-ascertainment, these incidence rates may still represent an underestimate of the "true" incidence of juvenile DM in the US. Nonetheless, the data reported here can be used to set a lower boundary for the incidence of this extremely rare condition, and thereby provide valuable data for health planners, as well as for clinicians.

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