Disease pattern of spondyloarthropathies in Spain: description of the first national registry (REGISPONSER)—extended report


Objective. The national registry of spondyloarthropathies (REGISPONSER) is launched to classify patients with this group of diseases treated in Spanish rheumatology clinics. This manuscript describes the methodological and organizational background as well as characteristics of patients finally included, and provides a comparative analysis between characteristics of both ankylosing spondylitis and undifferentiated spondyloarthropathy groups of patients.

Patients and methods. Twelve members of the GRESSER group have participated in the registry, for a one-year recruitment period. All consecutively registered adult patients treated in their clinics met the classification criteria of the European Spondyloarthropathies Study Group (ESSG). Data collected reflect the socio-demographic characteristics, as well as disease activity and functional status, clinical form at onset, treatment used and quality of life; all measured by standard instruments.

Results. Throughout 1 yr, 1385 patients have been included in the registry: 939 males (68%) and 440 females (32%), with an average age of 47 ± 13 years (mean ± s.d.), and an average disease duration of 12 ± 9 years. Diagnoses of the included patients were: AS (n = 842, 61%), PsA (n = 290, 21%), u-SpA (n = 205, 15%), reactive arthritis (n = 16, 1.2%), inflammatory bowel disease arthritis (n = 13, 0.9%) and JCA-spondyloarthropathy (n = 13, 0.9%). Regarding clinical form, 54% had axial disease, 20% peripheral disease, 24% mixed disease and 0.6% isolated enthesiitic form. Low-back pain was the first symptom reported in 53% of the patients, and most common extra-articular disease manifestations were psoriasis (25%), anterior uveitis (16%) and intestinal inflammatory disease (4%). Some kind of work disability was reported by 353 patients (25.5%).

Conclusions. Such databases are very useful to obtain information about characteristics of patients treated in a certain location or following a specific treatment practice, and provide a tool for assessing the impact of the disease. Data collected in this registry provide an appropriate clinical and demographic profile of patients suffering from SpA in Spain.

KEY WORDS: Spondyloarthropathies, Ankylosing spondylitis, Undifferentiated spondyloarthropathies, Epidemiology, Disease registry.

Introduction

Spondyloarthropathies (SpA) are a heterogeneous group of inflammatory interrelated diseases involving peripheral joints and spine and sharing similar clinical, epidemiological, radiological and immunogenetic features. Ankylosing spondylitis (AS) is the prototype disease of this group; other clinical entities include reactive arthritis (ReA), arthritis and spondylitis associated with psoriasis (PsA) or inflammatory bowel disease (IBD) and undifferentiated spondyloarthropathies (u-SpA) [1]. SpA prevalence has not been definitely established, as epidemiological studies have started focusing on this disease recently. Prevalence might be around 0.23–1.8% [2]. In Spain, there are no occurrence studies in the general population, but the National Study of Validation of SpA Classification Criteria [3] estimated a prevalence of 13% (range 8–16%) of patients with any SpA treated at rheumatology clinics. The prevalence of inflammatory low-back pain is 0.8% [95% confidence interval (CI): 0.6–1.0], as found in the EPISER study [4]. The clinical spectrum that defines patients with these diseases is very broad and includes four syndromes: (i) spinal, affecting sacroiliac joints and axial skeleton, (ii) peripheral arthritis, (iii) enthesitis and (iv) extra-skeletal, expressed with various degrees of intensity in different clinical entities.

Health care managers need reliable data from instruments to help them distribute and allocate health and social resources objectively and fairly. These instruments should be flexible and provide real-time data, and they should easily incorporate any changes in practice and scientific knowledge. Disease registries are more suitable for this task, as they provide real time data about frequency, geographic and temporary distribution, as well as disease pattern [5]. They inform about the case mix in different locations and provide an enlightening tool for assessing the impact of the disease and clinical practice variability. Furthermore, disease registries are an ideal source of random samples for cohort studies or case-control studies, the correct setting to test medical hypothesis [6]. There are many examples of large clinical databases in rheumatology [7], some of which also include genetic banks [8]. There are specific registries or databases such as those of paediatric rheumatic diseases [9], scleroderma [10] or rheumatoid arthritis [11] and psoriatic arthritis in North America [12]. There are also less specific registries, such as the National Databank of Rheumatic Diseases (NDBRD), developed in the USA [13] more than two decades ago, in which clinical information is compiled prospectively from many rheumatology clinics [14], or the National Database of German Arthritis Centres [6]. Clinical databases have been applied to evaluate surgical treatment outcomes [15] and monitor safety after the introduction of new expensive drugs [16, 17].
The experience with registries or large clinical databases in SpA is limited to a recently approved international registry of PsA [18] and a Finnish registry of twins with AS [19]. Our group aimed to design and develop an online registry of patients with SpA in our setting. The way to collect variables should be in agreement with major international working groups in SpA, namely ASAS, and simple enough so it can be feasible to adapt to clinical practice. The information collected should allow us to evaluate the SpA clinical pattern in our environment, and provide us with a representative population with SpA so as to draw random samples for future hypothesis-testing projects. The main aim of this project is to classify patients with SpA treated in Spanish rheumatology clinics. This manuscript describes a methodological and organizational background, general aims and uses and provides a description of patients finally included and a comparative analysis between characteristics of both AS and u-SpA groups of patients.

Patients and methods

In April 2004, the Spanish Spondyloarthropathies Study Group of the Spanish Society of Rheumatology (GRESSER) launched the National Spondyloarthropathies Registry (REGISPONSER). The registry is available through a computerized Internet database accessible to all participating members (http://biobadaser.ser.es/cgi-bin/regispenser/index.html). Twelve rheumatology departments from eight different cities were selected from those that have accepted to participate in the registry on the basis of the best availability to treat patients with spondyloarthritides. These centres represent a broad socio-demographic spectrum of the population treated by the Spanish Health System (Fig. 1). The average population covered by the participating hospitals is 800 000 (range 300 000–1 100 000), and includes urban and rural zones. All centres can be considered as a reference for rheumatic diseases in their area. All participating rheumatologists were required to include all patients registered consecutively that fulfilled the inclusion criteria. In their area. All participating rheumatologists were required to include all patients registered consecutively that fulfilled the inclusion criteria up to a minimum of 100 patients per centre.

Patients

The inclusion criteria were: (i) fulfilment of the classification criteria from the European Spondyloarthropathy Study Group (ESSG) [20]; (ii) blood tests available within 15 days of the inclusion visit, and a complete radiographic study within the previous year and (iii) agreement to complete all self-administered questionnaires. Each patient has been assigned a random code in the database to avoid entering personal data in the database. The inclusion period was set at 12 months. All patients gave their consent to participate in the study, which was approved centrally by the Ethics Committee of the University Hospital ‘Reina Sofia’.

Data collection

In each centre, there was a rheumatologist, previously trained in a 2-day session, responsible for the patient’s assessment and data entry in a centralized system of external monitoring to control inconsistencies or reliability of data collected and inclusion criteria. The socio-demographic information recorded was age, gender, employment-related variables and habits, especially regular exercise. An important batch of data was referred to the diagnosis: time (year) of the onset of SpA-specific signs and symptoms (inflammatory back pain, peripheral arthritis, extra-axial(extra)/skeletal affection), what specific signs and symptoms the patient had, when disease was diagnosed, how the patient responded to each ESSG criterion, what specific diagnosis the patient received (AS, u-SpA, PsA, IBD-associated arthritis or ReA), clinical form of the disease (axial, peripheral, enthesitic, extraarticular, or mixed) and whether the patient had family history of SpA. To ascertain the degree of the disease, the number of inflamed peripheral joints, the Maastricht Ankylosing Spondylitis Enthesis Score (MASES) [21], and the extra-articular disease manifestations were recorded by physical examination of the patient. For the evaluation of the disease status, the following anthropometrical measures were used: occipital-to-wall distance, modified Schober’s test, lateral flexion of lumbar spine, thoracic expansion, cervical rotation and finger-to-floor distance. We decided not to include the intermalleolar distance due to the difficulty in its measurement and to the high interobserver variability detected during the training session. As measures of disease status, we also included: night pain by a 0–10 visual analogue scale (VAS); physician and patient’s global assessment of disease activity, also by a 0–10 VAS; the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) [22] and functional capacity as scored by the Bath Ankylosing Spondylitis Functional Index (BASFI) [23]. Damage was accrued by the radiological assessment valued by the Bath Ankylosing Spondylitis Radiology Index (BASRI) [24], both for spine and total (BASRI spine + BASRI hips). The presence of erosions, osteophytes and protrusions in hips, were also assessed. Quality of life was additionally evaluated by the specific questionnaire of quality of life to spondyloarthritides (ASQoL) [25], and by the generic SF-12 [26], in which higher values indicate a better quality of life. Lab tests included the erythrocyte sedimentation rate (ESR), C-reactive protein (CRP) and HLA B27 status. Current treatment including non-steroidal anti-inflammatory drugs (NSAIDs), corticoids, disease-modifying anti-rheumatic drugs (DMARDs) and biological therapies were also recorded. The effectiveness of NSAIDs in relieving pain was defined as reduction of pain within 48 h after introducing them or rapid worsening within 48 h after discontinuing them. All data were collected in paper data forms, which were eventually entered into the online database, leaving the paper support available for monitoring.

Statistical analysis

The descriptive data are presented as a mean ± s.d. when referring to quantitative variables and as absolute frequencies and percentages when referring to the qualitative ones. Comparisons of continuous variables between groups were made by Student’s t-test and categorical variables by chi-square test. We calculated correlation coefficient and intraclass correlation coefficient (ICC).
with its corresponding 95% CI, considering that ICC values <0.5 represent poor or no agreement, values of 0.5-0.7 represent fair agreement and values >0.7 represent good agreement. Statistical analysis was performed using SPSS 11.0 (SPSS Inc. Chicago, IL, USA). A two-sided value of P < 0.05 was considered significant.

Results

The results referred to all patients included in the registry and classified according to their specific diagnosis

After 12 months (April 2004 to March 2005), 1385 patients were included in the registry. Of these, 1379 patients fulfilling ESSG criteria [27] were found acceptable for inclusion (six patients had been erroneously classified). Of these, 939 were males (68%) and 440 females (32%), with an average age of 48 ± 13 (range 12-88).

The specific diagnoses were: AS in 842 patients (61.1%), PsA in 290 (21.0%), u-SpA in 205 (14.9%), ReA in 16 (1.2%), IBD-associated arthritis in 13 (0.9%) and juvenile SpA in 13 (0.9%). Most patients (n = 723, 52.4%) were employed fully at the time of inclusion, 119 (8.6%) were housewives and 498 (36.1%) were unemployed. As many as 351 (26.5%) presented some sort of life-long occupational disability, of whom 54 (3.9%) were temporarily disabled from working as from the day of inclusion, 60 (4.4%) were permanently, partially disabled (i.e. unable to perform heavy duty jobs), 76 (5.5%) were permanently, totally disabled (unable to perform usual tasks, but suited for others), 152 (11%) were totally disabled from work of any kind and 9 (0.7%) were absolutely disabled, which means that aid in daily life tasks is required.

Table 1 shows average values of age, disease duration (from diagnosis) and diagnosis delay for all included patients according to the diagnostic group. Also, time of evolution of the disease defined as time from early signs/symptoms attributable to the disease. The average age at disease onset was 29.5 ± 12 (range 4-80 yrs) for the patients as a whole, and 26.1, 39.9 and 30.1 yrs for AS, PsA and u-SpA, respectively. In 23.2% of the patients, the delay was under 1 yr, whereas in 20.6% it was over 10 yrs. The average age at diagnosis was 36 yrs and the average diagnosis delay was 6.5 yrs, with remarkable differences between diseases: 8 yrs for AS, 3.8 for PsA and 4.5 for u-SpA.

The percentage with disease onset in childhood (age <16 yrs) was 7.0%, whereas the percentage of late onset (age >40 yrs) was 18%. There was no difference in average age at disease onset between male (25.7 yrs) and female (26.9 yrs) AS patients.

The earliest symptoms related to SpA were, in decreasing order: low-back pain (52.5%), lower limbs arthritis (27.4%), sacroiliac syndrome, defined as alternate or non-specific buttock pain (24.4%), upper limbs arthritis (16.1%), enthesitis (7.5%), neck pain (5.7%), coxitis (2.7%) and dactylitis (1.8%).

During the course of the disease, patients presented: inflammatory spinal pain (n = 1078; 78.2%), peripheral arthritis (n = 648; 47.0%), alternating buttock pain (n = 614; 44.5%) and enthesitis (n = 379; 27.5%). An episode of urethritis, cervicitis, or acute diarrhoea had occurred in 26 patients (1.9%) within the month prior to the development of arthropits.

The associated extra-articular manifestations were, in descending order: psoriasis (25%), anterior uveitis (16%), involvement IBD (4%), prostatitis (1.2%), heart disease (1.2%), lung disease (1.1%), renal disease (1.0%), balanitis (0.9%), palmoplantar pustulosis (0.8%), acne conglobata (0.6%) and neurological involvement (0.3%). A family history of SpA was present in 224 (16.2%) patients.

Table 2 illustrates the pattern of clinical expression and characteristics of the disease in patients as a whole and by diagnosis group. Regarding the clinical form of the disease, 53.5% of the patients had mainly axial disease, 20.4% had peripheral form, 24.3% had mixed form and only 0.7% of the patients had a predominantly enthesitic disease. Table 2 also summarises metropolitical parameters.

Table 3 expresses data of disease activity. Most of the patients included in the registry showed elevated values of the CRP and ESR; in particular, patients with ReA and juvenile SpA exhibited higher values of CRP. The average high value of the nocturnal
pain was prevalent in the AS patients, while the low value was common in the juvenile SpA. We observed that physicians assessed less thoroughly the activity of the disease across all patients included than patients did.

In Table 4, we included different treatments patients received at the time of the inclusion visit. In the case of biologicals, current treatment was not only included, but also any other treatment previously administered. NSAIDs had a positive effectiveness in 860 (62.4%) of the patients, showing slight differences in response depending on the diagnosis: AS 526 (62.5%), PsA 174 (60.0%), u-SpA 139 (67.8%) and others 21 (50%). Less than half of the patients (n = 477; 34.6%) practised regularly some type of physical exercise.

**Comparison of AS and u-SpA patients**

**Clinical data.** As we see in Tables 2 and 3, patients with AS had a smaller value in the Schober’s test, a smaller mobility of the cervical lateral rotation, a greater fingers-to-floor and occiput-to-wall distance, a higher degree of pain in the VAS and the global assessment of the disease by the physician than the group of patients with u-SpA, who presented better values with respect to the thoracic expansion.

**Demographic data.** Figure 2 presents the results of the comparative analysis of average values of age, age at onset and at diagnosis, time of evolution, disease duration and diagnosis delay between the groups of patients with AS and u-SpA. Patients with AS had a greater time of evolution, diagnosis delay, a longer duration of the disease and a greater age at inclusion time. We did not find any differences between two groups concerning age at diagnosis. Age at onset of the disease is smaller in the group of patients with AS than in patients with u-SpA.

**Disease activity.** Data corresponding to the comparisons of the variables BASDAI, BASFI, BASRI and AsQol for patients with AS and u-SpA are expressed in Fig. 3, based on the time of evolution divided in three sections: <5 yrs, between 5 and 10 yrs and >10 yrs. Average value of BASFI in patients with AS is greater than that presented by patients with u-SpA (3.6 ± 2.7 vs 2.6 ± 2.5). Nevertheless, this relation is exactly opposite when time of evolution of disease is considered to be <5 yrs (2.0 ± 2 vs 3.0 ± 2.7). The comparison of the average values of BASDAI

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**Table 3. Characteristics of 1379 patients with spondyloarthropathies, by specific diagnosis.**

<table>
<thead>
<tr>
<th></th>
<th>AS (n = 842)</th>
<th>PsA (n = 290)</th>
<th>u-SpA (n = 205)</th>
<th>ReA (n = 16)</th>
<th>a-IBD (n = 13)</th>
<th>Juvenile SpA (n = 13)</th>
<th>Total (n = 1379)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nocturnal back pain (cm)</td>
<td>4.0 ± 3.0</td>
<td>2.7 ± 3.0</td>
<td>3.7 ± 3.0</td>
<td>3.4 ± 3.4</td>
<td>2.6 ± 3.3</td>
<td>1.9 ± 2.7</td>
<td>3.6 ± 3.0</td>
</tr>
<tr>
<td>Patient Global Assessment (cm)</td>
<td>4.6 ± 2.8</td>
<td>4.4 ± 2.8</td>
<td>4.3 ± 2.8</td>
<td>4.3 ± 3.0</td>
<td>3.5 ± 3.4</td>
<td>3.2 ± 2.1</td>
<td>4.5 ± 2.8</td>
</tr>
<tr>
<td>Physician Global Assessment (cm)</td>
<td>3.1 ± 2.2</td>
<td>2.5 ± 2.0</td>
<td>2.8 ± 2.1</td>
<td>2.6 ± 2.6</td>
<td>2.1 ± 1.6</td>
<td>2.8 ± 2.4</td>
<td>2.9 ± 2.1</td>
</tr>
<tr>
<td>ESR (mm/h)</td>
<td>18.7 ± 16.9</td>
<td>19.0 ± 15.4</td>
<td>16.7 ± 12.6</td>
<td>12.3 ± 10.3</td>
<td>23.0 ± 28.2</td>
<td>22.7 ± 24.7</td>
<td>18.5 ± 16.2</td>
</tr>
<tr>
<td>CRP (mg/dl)</td>
<td>9.9 ± 16.8</td>
<td>8.1 ± 10.6</td>
<td>7.4 ± 14.9</td>
<td>25.2 ± 44.3</td>
<td>11.1 ± 10.0</td>
<td>23.0 ± 42.1</td>
<td>9.5 ± 16.6</td>
</tr>
<tr>
<td>HLA B27 positive, n (%)</td>
<td>658/782 (84)</td>
<td>36/164 (22)</td>
<td>131/185 (71)</td>
<td>9/164 (6)</td>
<td>4/10 (4)</td>
<td>11/12 (92)</td>
<td>849/1167 (73)</td>
</tr>
<tr>
<td>Physical component SF12</td>
<td>37.6 ± 7.6</td>
<td>38.2 ± 8.4</td>
<td>38.5 ± 7.7</td>
<td>43.0 ± 9.2</td>
<td>38.0 ± 8.0</td>
<td>40.5 ± 9.1</td>
<td>38.0 ± 7.8</td>
</tr>
<tr>
<td>Mental component SF-12</td>
<td>50.6 ± 5.5</td>
<td>50.3 ± 6.2</td>
<td>49.9 ± 5.6</td>
<td>50.9 ± 6.4</td>
<td>48.8 ± 5.7</td>
<td>53.2 ± 5.1</td>
<td>50.4 ± 5.7</td>
</tr>
</tbody>
</table>

Results are expressed as a mean ± s.d. unless otherwise specified. ESR, erythrocyte sedimentation rate; CRP, C-reactive protein.

**Table 4. Current treatment used by 1379 Spanish patients with SpA at day of inclusion.**

<table>
<thead>
<tr>
<th></th>
<th>AS (n = 842)</th>
<th>PsA (n = 290)</th>
<th>u-SpA (n = 205)</th>
<th>ReA (n = 16)</th>
<th>a-IBD (n = 13)</th>
<th>Juvenile SpA (n = 13)</th>
<th>Total (n = 1379)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSAIDs</td>
<td>584 (69)</td>
<td>175 (60)</td>
<td>141 (69)</td>
<td>9 (56)</td>
<td>4 (31)</td>
<td>8 (62)</td>
<td>921 (66.8)</td>
</tr>
<tr>
<td>Glucocorticoids</td>
<td>51 (6)</td>
<td>54 (19)</td>
<td>26 (13)</td>
<td>1 (6)</td>
<td>0</td>
<td>2 (15)</td>
<td>136 (9.9)</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>56 (7)</td>
<td>125 (43)</td>
<td>23 (11)</td>
<td>1 (6)</td>
<td>0</td>
<td>5 (38)</td>
<td>210 (15.2)</td>
</tr>
<tr>
<td>Sulphasalazine</td>
<td>98 (12)</td>
<td>24 (8)</td>
<td>21 (10)</td>
<td>1 (6)</td>
<td>0</td>
<td>2 (15)</td>
<td>150 (10.9)</td>
</tr>
<tr>
<td>Leflunomide</td>
<td>4 (0.5)</td>
<td>13 (4)</td>
<td>2 (1)</td>
<td>1 (6)</td>
<td>0</td>
<td>0 (1)</td>
<td>20 (1.5)</td>
</tr>
<tr>
<td>Infliximab*</td>
<td>115 (14)</td>
<td>17 (6)</td>
<td>10 (5)</td>
<td>1 (6)</td>
<td>0</td>
<td>3 (23)</td>
<td>150 (10.9)</td>
</tr>
<tr>
<td>Etanercept*</td>
<td>24 (3)</td>
<td>18 (6)</td>
<td>2 (1)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>44 (3.2)</td>
</tr>
</tbody>
</table>

Dates are expressed as n (%). NSAIDs, non-steroidal anti-inflammatory drugs.
*Previously administered.

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**FIG. 2.** Comparison of average values of age, age at diagnosis, age at onset, time of evolution, disease duration and diagnosis delay of patients with AS and u-SpA. The P-value represents significance of difference in mean values as determined by Student’s t-test.
between both groups of patients shows the same behaviour as with BASFI but without showing significant statistical differences neither in the total number of patients (4.1 ± 2.3 vs 4 ± 2.4) nor in any group per time of evolution. On the contrary, the average values of BASRI total 7.4 ± 3.9 for patients with AS and 2.3 ± 2.0 for patients with u-SpA differ significantly among the group as a whole and between all groups per time of evolution (<5 yrs: 4.1 ± 2.2 vs 1.5 ± 1.6; 5–10 yrs: 4.9 ± 2.5 vs 2.2 ± 1.6; >10 yrs years: 8.0 ± 4.0 vs 2.8 ± 2.1).

Value of the patient’s opinion. We have calculated the degree of agreement between the patient global assessment (PGA) of the disease and the nocturnal back pain (NBP) with BASDAI in patients with AS and u-SpA. We classified the results into three groups (<5 yrs, 5–10 yrs and >10 yrs), according to time of evolution of the disease and agreement degree determined by means of the ICC with its corresponding 95% CI. Table 5 shows the results: the agreement between PGA and BASDAI is higher in the u-SpA group and slightly lower in the AS group, at any time of disease duration. The agreement of the BASDAI with NBP is higher in the u-SpA group with >10 yrs of evolution and fair in the others.

Discussion

REGISPONSER is a dynamic project based upon a disease registry. The presented results provide a reliable picture of SpA in Spain, as the data were gathered from a large and representative population of patients.

Disease registries are valuable instruments for clarifying aspects of the epidemiology, outcome, effectiveness and therapeutic tolerance of diseases, as well as their impact on socioeconomic conditions and quality of life. Such registries are usually built prospectively around large databases that gather information from many centres. And in a standardized form, REGISPONSER is the first registry designed specifically for SpA, which collects the minimum set of data (socio-demographic, clinical, biological and genetic) relevant to the disease. Furthermore, we have designed a system that allows inclusion of patients from any rheumatology department of Spain under strict quality control by means of close monitoring and filters that detect data inconsistencies. All data collecting forms used in the registry were agreed upon beforehand, and they have been adapted to improve ease of use in regular clinical practice. One of the most important achievements is the normalization of SpA patients’ assessment and the incorporation of self-administered patient questionnaires into routine.

![Comparison of average values of BASFI, BASDAI, BASRI and AsQuol of AS and u-SpA patients. The P-value represents significance of difference in mean values as determined by Student’s t-test.](image-url)
clinical practice. Furthermore, each rheumatologist has individual access to the registry, either for investigative or management purposes, making it an effective tool for supporting the decision-making process. It is now clear that uniformity in data collection using similar methodologies will enhance the power and comparability of data obtained from different sources. It is important that future researchers build upon common methodologies in order to use optimal strategies and learn about experiences in other parts of the world.

We have not found similar published studies of patients with SpA that can be compared with ours. In this respect, it is interesting to emphasize that although the registry is the first SpA database, we have noted that the distribution by centres and 10 Latin American countries.

At the moment, the registry is being used in 50 new Spanish centres and 10 Latin American countries.

The authors have declared no conflicts of interest.

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