

The Population Based Studies in Rheumatoid Arthritis. A Method of Longterm Followup Studies

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ABSTRACT. This article describes the aim, organization, data collection, and selected results from the Oslo Rheumatoid Arthritis Register (ORAR). The ORAR was established in 1994 and is annually updated with new and diseased cases. Inclusion criteria were a diagnosis of rheumatoid arthritis (RA) and a residential address in Oslo. As of January 1, 1994, Oslo had 477,781 inhabitants, 2 centers providing rheumatological health services, in close collaboration with general practitioners, and no fulltime private practising rheumatologists. Patients with RA ever treated in one of the 2 hospitals were identified and enrolled in ORAR. We assumed that patients in ORAR represented the majority of patients with RA in the county. Data collections have been performed as mail surveys and clinical examinations. By January 1, 1994, 1552 RA patients were included in the register; currently, 1626 are included. The completeness of the register has been estimated to be about 85%, based on a population survey. Response rates in ORAR surveys and clinical examinations have been between 60% and 80%. Results have been provided, for example, on incidence and prevalence linked to health outcomes, performance of health status measures, and occurrence of osteoporosis and secondary Sjögren's syndrome. The ORAR has provided epidemiological data that is representative of the entire patient population in the county. (J Rheumatol 2004;31 Suppl 69:35-40)

Key Indexing Terms:

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OSTEOPOROSIS

A wide spectrum of areas within rheumatoid arthritis (RA) serve as targets for epidemiological research, e.g., criteria, occurrence, etiological factors, mortality, and morbidity. During the last 10 or 15 years, several major epidemiological advances in RA have been achieved, including revised classification criteria for RA¹, core sets for assessment of disease activity^{2,3}, response criteria for the assessment of drug efficacy⁴, and agreement on a core set of measures for longitudinal observational studies⁵.

From studies on reactive arthritis in the late 1980s and early 1990s⁶ we knew that the County of Oslo could serve as a reliable setting for epidemiological studies in rheumatology. The general aim of the Oslo Rheumatoid Arthritis Register (ORAR) was to provide epidemiological data from patients with RA that could contribute to health care planning and improved clinical management of these patients. Our goal was to study samples of patients with RA being representative of the entire patient population in the county.

METHODS

Setting and case identification. ORAR was established in 1994. Inclusion criteria were a diagnosis of RA¹ and a resi-

dential address in Oslo. Patients with juvenile arthritides, i.e., disease onset before the age of 16, were excluded.

On January 1, 1994, Oslo had 477,781 inhabitants, of whom 356,486 were between 20 and 79 years of age. Rheumatology service in Oslo was provided by 2 units. The Department of Rheumatology at Diakonhjemmet Hospital had the responsibility for the care of rheumatic patients from the entire city of Oslo, with short waiting lists and good access to specialized care. Oslo Sanitetsforening Rheumatism Hospital had the major responsibility as a referral center for the whole country, especially focusing on childhood arthritis and complicated surgery in rheumatic diseases. However, some RA patients with residential address in Oslo also had their longterm and outpatient service at the latter hospital. Thus, to ensure complete registration of patients with RA with a residential address in Oslo, we had to identify all patients being treated in both Diakonhjemmet Hospital and in the Oslo Sanitetsforening Rheumatism Hospital. In 1994 no fulltime private practising rheumatologists were working in Oslo.

A variety of electronic and hand search procedures were performed to identify possible candidates for inclusion in the register. Hospital charts from 1980 in the 2 rheumatology departments in Oslo with an *International Classification of Diseases* ICD-9 diagnosis of 714.0 (RA) or 714.9 (unspecified polyarthritis) were initially reviewed, as were referrals to members of the multidisciplinary team in the Diakonhjemmet Hospital (physiotherapists, occupational therapists, and social workers). With permission from the Data Inspectorate, patients were included retrospectively

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Table 1. Collection of data in the Oslo Rheumatoid Arthritis Register showing the number of patients invited/attending (%) and the measures used in the 5 waves of data collection.

| Domain Measure | 1994, | Mail Surveys | 2001, | Clinical Examination | 1998–99, |
|---|-------------------------|----------------------------------|------------------------|-----------------------------------|-----------------------|
| | n = 1552/1024 (66.0) | 1996, n = 1620/1153 (71.2) | n = 1626/965 (59.3) | 1996–97, n = 894/636 (71.1) | n = 502/414 (82.5) |
| Demographic | | | | | |
| Age | • | • | • | • | • |
| Sex | • | • | • | • | • |
| Marital status | • | • | • | • | • |
| Disease duration | • | • | • | • | • |
| Education | • | • | • | • | • |
| Smoking | • | • | • | • | • |
| Exercise | • | • | • | • | • |
| Employment/occupation | • | • | • | • | • |
| Comorbidities | • | • | • | • | • |
| BMI | • | • | • | • | • |
| Other lifestyle variables | • | • | • | • | • |
| Health Status | | | | | |
| MHAQ | • | • | • | • | • |
| HAQ | • | • | • | • | • |
| AIMS-2 | • | • | • | • | • |
| SF-36 | • | • | • | • | • |
| Pain VAS | • | • | • | • | • |
| Fatigue VAS | • | • | • | • | • |
| Headache VAS | • | • | • | • | • |
| Other symptoms VAS | • | • | • | • | • |
| Priorities for improvement | • | • | • | • | • |
| Health satisfaction/expectations | • | • | • | • | • |
| Disease process | | | | | |
| Self-reported joint counts | • | • | • | • | • |
| 28 swollen joint count | • | • | • | • | • |
| 28 tender joint count | • | • | • | • | • |
| Patient global | • | • | • | • | • |
| Investigator global | • | • | • | • | • |
| ESR | • | • | • | • | • |
| CRP | • | • | • | • | • |
| Rheumatoid factor | • | • | • | • | • |
| Grip strength | • | • | • | • | • |
| Tender points | • | • | • | • | • |
| OA in finger joints | • | • | • | • | • |
| Damage | | | | | |
| 18–deformed joint count | • | • | • | • | • |
| Joint replacement count | • | • | • | • | • |
| Hand radiographs | • | • | • | • | • |
| Extraarticular complications | • | • | • | • | • |
| Coping | | | | | |
| Self-efficacy scales | • | • | • | • | • |
| RAI-5 | • | • | • | • | • |
| Cost/health services | | | | | |
| General practitioner contacts | • | • | • | • | • |
| Rheumatologist contacts | • | • | • | • | • |
| Utilization of other health care services | • | • | • | • | • |
| Involvement in care | • | • | • | • | • |
| Satisfaction with care | • | • | • | • | • |
| Use of antirheumatic medication | • | • | • | • | • |
| Use of osteoporosis medication | • | • | • | • | • |
| Disease related direct costs | • | • | • | • | • |
| Osteoporosis | | | | | |
| DEXA | • | • | • | • | • |
| MXA | • | • | • | • | • |
| History of fractures | • | • | • | • | • |
| Spine radiograph | • | • | • | • | • |
| QUS (calcaneus) | • | • | • | • | • |

Table 1. Continued.

| Domain Measure | Mail Surveys | | | Clinical Examination | |
|------------------------------------|----------------------------------|----------------------------------|---------------------------------|-----------------------------------|-----------------------------------|
| | 1994, n = 1552/1024 (66.0) | 1996, n = 1620/1153 (71.2) | 2001, n = 1626/965 (59.3) | 1996–97, n = 894/636 (71.1) | 1998–99, n = 502/414 (82.5) |
| Sjögren's syndrome | | | | | |
| Sicca symptoms | | • | • | • | |
| Saliva production | | | | • | |
| Schirmer test | | | | • | |
| GI problems | | | | | |
| Abdominal discomfort VAS | | • | • | • | • |
| History of GI ulcer complications | | | • | • | |
| Use of gastroprotective medication | | | • | | |

BMI: body mass index; MHAQ: Modified Health Assessment Questionnaire; HAQ: Health Assessment Questionnaire; AIMS-2: Arthritis Impact Measurement Scales-2; SF-36: Medical Outcome Study Short-Form-36; VAS: visual analog scale; ESR: erythrocyte sedimentation rate; CRP: C-reactive protein; RAI: Rheumatology Attitude Index; DEXA: dual energy x-ray absorptiometry; MXA: morphometric x-ray absorptiometry; QUS: quantitative ultrasound; GI: gastrointestinal.

into the register database. Disease onset was recorded as the date when at least 4 out of 7 classification criteria of RA¹ were fulfilled. By January 1, 1994, 1552 RA patients were included in the register. Out of these, 1333 were between 20 and 79 years of age.

The register has been updated annually by enrolling new cases with RA being referred to the Department of Rheumatology at Diakonhjemmet Hospital. Further, addresses have been updated and the register has annually been checked against the population register to identify patients. Over the years the register has comprised rather stable numbers of patients. As of January 1, 2001, the number of enrolled RA patients was 1626.

Is the register population based? We assumed that almost all patients with RA in Oslo had been treated in either Diakonhjemmet or Oslo Sanitetsforening Rheumatism Hospital, i.e., that the register should be representative for the underlying patient population in the County of Oslo. This assumption was tested in a population survey⁷. A 4-page questionnaire was mailed to 10,000 randomly selected individuals between 20 and 79 years of age. Respondents reported on musculoskeletal pain, stiffness, and rheumatic diagnoses from an 11-item checklist, as well as on disability and mental distress. Of 5886 respondents, 158 patients (2.7%) reported having RA diagnosed by a physician (n = 107) and/or according to their own opinion (n = 142). RA was confirmed in 35 of these 158 individuals⁸. All patients with self-reported RA were checked against ORAR. Thirty out of the 35 patients with confirmed RA were identified in the register and the remaining 5 patients were diagnosed after a clinical, laboratory, and radiographic examination. Thus, 5 out of the 35 RA patients identified from a population survey of 10,000 random subjects between 20 and 79 years were not enrolled in the register. From this result we have assumed that the completeness of the register is about 30/35, i.e., 85%⁹.

Data collection. Several waves of data collection have been performed since 1994. Mail surveys to the entire patient population were performed in 1994, 1996, and 2001. The response rates in these mail surveys have been around 60–70%. In addition, 2 waves of clinical examinations have been performed, but this part has been restricted to patients born in 1926 and later. The first clinical examination was performed in 1996–97, with a subsequent 2-year followup, and comprised a complete clinical examination with joint counts, assessment of health related quality of life, and different measures focusing on complications of RA with special emphasis on secondary Sjögren's syndrome (SS) and osteoporosis. The clinical measurements are performed by specially trained research nurses under supervision of rheumatologists.

In general, we have attempted to incorporate measures included in the recommended core set for longitudinal observational studies⁵, but have also focused on selected research issues. An overview of the waves of data collection as well as the main variables is shown in Table 1.

SELECTED RESULTS

The research has especially focused on descriptive epidemiology linking the numbers of occurrence with disease variables, examination of the performance of health status measures, studies on psychosocial disease factors, as well as occurrence of selected disease manifestations, e.g., secondary osteoporosis and secondary SS.

We have been able to show that the prevalence of RA in the county of Oslo is around 0.5%⁹. This number is based on both the population survey and the data from the register. The 35 RA patients from the population survey and the 1333 patients from the ORAR had remarkably similar demographic and disease variables⁹.

The incidence of RA in Oslo was 25 per 100,000, with age related incidence very similar to other recent studies^{10,11}.

About half of the patients will have severe disease after about 3 years¹².

The large amount of data on health related quality of life (Table 1) has provided an opportunity to examine the performance of health status measures^{13,14} and to link the scores to the prevalence⁹ and incidence¹² numbers. In the study of prevalence we showed that about half of the patients had modified Health Assessment Questionnaire (MHAQ) scores exceeding 1.5 (range 1–4), indicating a disease with an increased risk of reduced life expectancy¹⁵ and with an assumed need for longterm health care⁹. Based on these and other data from the ORAR it could be assumed that around 750 patients with RA in Oslo will need longterm surveillance in a specialized rheumatological health service. After 5 year followup of the incidence cohorts a clinically important effect on physical function (MHAQ > 1.5) was seen in 38% of the patients, on social functioning [Arthritis Impact Measurement Scale 2 (AIMS-2) social > 4] in 50%, on mental distress (AIMS-2 affect > 4) in 27%, on pain [visual analog scale (VAS) > 40 mm] in 35%, and on fatigue (VAS > 40 mm) in 41%¹².

We have also used data from clinical examinations combined with the known prevalence to estimate the proportions of patients with RA that could be candidates for treatment with tumor necrosis factor-blocking agents. These results indicated that up to 15% of RA patients between 20 and 70 years could be considered as candidates for such therapy¹⁶.

Measures on disease process, joint damage, health status, and self-efficacy have been compared between patients with RA living in an affluent versus a less affluent area¹⁷. Patients with RA in 2 socioeconomically different areas in Oslo were found to be equal regarding disease process and joint damage measures. However, in the measures reflecting physical and psychosocial health status, patients in the less affluent area seemed to be more seriously ill. They also had lower self-efficacy scores, reflecting less confidence in their ability to influence the disease¹⁷.

Since our patient samples are not true inception cohorts, we have not been able to do major studies on factors that can trigger RA. However, in one study we combined data from the incidence cohort and the population survey to examine risk factors for RA. This study showed that age, female sex, and current smoking were risk factors for RA, and that smoking was especially evident as a risk factor in men with seropositive RA¹⁸.

In studies on SS it was shown that sicca symptoms were reported in 38% of the patients. Reduced tear production was present in 29%, and reduced saliva production in 17%. The minimum frequency of secondary SS was 7%. Measurements of exocrine disease manifestations were to variable extents bivariately correlated to disease activity measures, physical disability, pain, fatigue, and use of xerogenic drugs¹⁹.

Secondary osteoporosis is a well known complication to RA. Our studies have shown a 2-fold increased occurrence both in female and male RA patients²⁰. Studies are now in progress to examine the occurrence of vertebral deformities, nonvertebral fractures, and their relationships to bone measurement and clinical and demographic variables. In these latter studies, the epidemiological approach has been extended to examining healthy controls matched to individual ORAR patients according to sex, age, and residential area (the latter as a surrogate marker for socioeconomic status). These control subjects are recruited from the national population register.

Recently, patients from the ORAR have been used as age and sex matched controls to smaller patient samples with either patients with other rheumatic disease or with RA patients from other countries. These comparative studies have revealed differences in health effects²¹ and osteoporosis²² between RA and systemic lupus erythematosus, and revealed differences in disease characteristics across countries of importance to understand the burden of the diseases^{23,24}.

DISCUSSION

If the results of our study are to be generalized, the study samples need to be representative. Both left and right censorship²⁵ may constitute bias in the studies from ORAR. Left censorship in longitudinal studies refers, for example, to the potential bias introduced when patients are recruited at some stage after disease onset. Right censorship relates to the potential loss of patients caused by followup bias.

Being not truly population based, left censorship in terms of completeness of the captured RA population was examined by the population survey, indicating an 85% completeness of the register^{8,9}. We therefore have to take into account at least a 15% underestimation of incidence and prevalence numbers from our studies. Further, older patient groups have been excluded in many of the studies, for practical, medical, and biological reasons. For example, the validation of the completeness of ORAR was performed for the age group 20–79 years⁹, and patients exceeding 70 years of age were not included in the clinical examinations¹⁹.

Right censorship bias must be suspected in the followup of patients. Dropouts that occur due to noncompliance, other illnesses, or death are non-random²⁶. Between 30% and 40% of the patients have been lost from the various data collections. However, only minor differences have been observed between respondents and nonrespondents, for both demographic and clinical characteristics, although respondents in all studies have tended to be younger than nonrespondents.

Another issue is related to the correct identification of patients to be included in the register. Left censorship bias may occur because patients die before referral, and thus inclusion in the register. It is also possible that some patients

improve, and thus they are also not referred to the rheumatological service.

The cumulative approach chosen in ORAR for classification of RA¹ has advantages compared to the “current RA status”²⁷. In another study the incidence of RA rose by 23% in women and 42% in men when patients were given 5 years from disease onset in which to satisfy the criteria cumulatively²⁸. It is therefore not likely that any major proportion of RA patients was missed due to a too-rigid implementation of the classification criteria.

There may rather be some overestimation due to incorrect diagnosis. The specificity of the classification criteria is not 100%, and individuals without RA may have been included into the ORAR. Clinical examinations in ORAR revealed uncertainty about fulfilment of at least 4 out of 7 items in the classification criteria in 10–15% of the patients.

Some recent concerns are related to legal, ethical, and administrative issues. The approval and use of patient registers are currently under debate in Norway. In particular, longterm followup of register patients is a concern that is continuously followed by the Data Inspectorate, as well as how the data are stored and linked to information in other registers. In principle, we consider our register a research tool, but also a tool to monitor the results of the management program of RA patients in our county. Thus, the results are also relevant for evaluation of the quality of care. These aspects will be increasingly important with the availability of longterm followup data.

All data collections have to be approved by the ethical committee. Attendance at clinical examinations and completion of questionnaires has to be strictly voluntary, and non-attendance should not influence the access to regular consultations and therapy. Some patients complain about large amounts of questionnaires, and a somewhat lower response rate in our most recent mail survey (59% compared to 66% in 1994) may indicate that we are close to exceeding the threshold that is acceptable for the patients.

Until now, patients with RA have been treated in their county of residence. A new Norwegian law about patients' rights²⁹ indicates that patients may be free to choose the hospital that they prefer based on waiting lists, quality of care, and other variables that may influence their choice. This “free choice of hospital” system may influence the future completeness of the register.

Results from studies published from ORAR must be interpreted on the background of some of the above methodological concerns. However, since the ORAR was established, many results from our own as well as other epidemiological studies have influenced the understanding of the disease burden of RA and the factors contributing to disease manifestations. Such results have been used in health care planning, both in our hospital and elsewhere in Norway, to target disease management according to the needs of patients.

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