Treatment of Rheumatoid Arthritis in Cross-sectional Analysis: Vilnius Rheumatoid Arthritis Register-based Study

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Objective. To analyze the treatment specificities of rheumatoid arthritis (RA) patients in Vilnius.

Materials and methods. The treatment of RA patients was analyzed using the data of the Vilnius RA Register established in the end of 1998 and comprising 1018 RA outpatients from 486,506 adult Vilnius citizens. The patients are registered when complying with the ACR'88 RA classification criteria and if they are the citizens of Vilnius at the time of the survey. Through the period from 1999 to 2001, 404 Vilnius RA patients were surveyed and examined.

Results. Practically all the patients (98.3%) were treated in the past or currently with non-steroidal anti-inflammatory drugs (NSAIDs). Almost half of the patients (42%) take corticosteroids constantly. 53.5% of the patients had had intra-articular steroid injections in the past. 85.6% of RA patients at some point of time were treated with the disease-modifying antirheumatic drugs (DMARDs), but at the time of the survey only 46.3% were taking DMARDs. DMARDs were prescribed to 62.9% of those with the disease duration less than 4 years and considerably less often to those who had been ill for more than 10 years (37.1%, $p = 0.00$). Sulfasalazine is the most popular drug of this group. It was prescribed to 47% of the patients and at the time of the survey 19.6% were taking it. Currently, methotrexate is the second by frequency taken drug. The antimalarial drugs are used for the longest period of time – 20 months on the average. Side effects of the drugs were mentioned more frequently in comparison to the other known reasons for termination such as lack of efficiency, termination by patient's own decision, switching to another DMARD, etc.

Conclusion. As a rule, the second line drugs were prescribed to the patients who had been ill for a short period of time. Sulfasalazine is the most commonly taken DMARD. The antimalarial drugs are the ones with which the patients are cured for the longest period of time. The reasons for the termination of the treatment with DMARDs generally remained unknown; the side effects of the drugs were mentioned more frequently in comparison to the other known reasons.

Key words: rheumatoid arthritis, treatment, disease-modifying drugs, RA Register

INTRODUCTION

During the last two decades the pharmaceutical treatment of rheumatoid arthritis has notably changed. Until the end of the 1980s the majority of the rheumatologists followed the "pyramid" principal when patients first were treated by better-tolerated but far less effective drugs and more effective and more toxic drugs were prescribed later (1). Today voices are clearly given for early and rather aggressive RA treatment at the beginning of the illness, because it has been proven that the results are far better when the DMARDs are prescribed in the early stage of the disease than later (2–8). When the DMARDs

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are started later (in the second, third years of the disease), the remissions are far more rare; in the best case the treatment only slows down but not blocks the progress of the disease; morphologic changes in X-ray pictures multiply over and over (9–10). The treatment recommendations are usually based on the conclusions of randomized clinical studies and seldom on sectional studies (11–12). Up to now, it is not much known about how the results of the trials get their resonance in the daily rheumatologic practice.

The goal of the present work was to analyze the treatment of RA patients in Vilnius in a cross-sectional study. For that purpose the data of the Vilnius RA Register were used.

MATERIALS AND METHODS

The analysis of the treatment of RA patients was performed using the data of the Vilnius RA Register established late in 1998 and comprising 1018 RA patients out of 486,506 adult Vilnius citizens. The Vilnius RA Register is annually updated with the new cases of the disease, changes caused by death or departure from the city. The patients are registered when complying with the ACR'88 RA classification criteria and if they are the citizens of Vilnius at the time of the survey.

The rheumatologist asked the patients for their consent, and those who agreed to participate in the survey were clinically examined. The survey consisted of the questions concerning social demographic status, including age, sex, nationality, marital status, education, profession, working capacity, duration of the disease; previous and current pharmaceutical treatment, its duration, and reasons for the termination of treatment, intra-articular injections, surgical treatment. The survey about the treatment consisted of questions concerning each DMARD, that is, chloroquine or hydroxychloroquine, gold preparations, penicillamine, methotrexate, azathioprine, cyclophosphamide, sulfasalazine and cyclosporine. The patients were questioned whether they had been taking these drugs in the past and how long and whether they were taking them at the time of examination. If the treatment with one of the drugs was finished, the possible reasons for the termination of the treatment were recited and the patient was asked to choose one of the variants: reasons unknown, side effects of the drug, finished course of the treatment, treatment in the clinic was not extended, inefficient, the patient could not buy the medicine, the drug was substituted for another DMARD, the patient himself cancelled the treatment. It was also questioned whether intra-articular injections were ever performed, how many times and into what joints. While analyzing NSAIDs and corticosteroids, the patients were questioned whether they took these drugs, if the answer was positive – how long; they were also asked to choose one of the variants: take the drug only during the flare-up, constantly, inconstantly. The patients were asked if synovectomy, operation of joint prosthesis or any other surgical intervention whad been performed.

Hereby, 404 citizens of the city of Vilnius with RA were surveyed and examined.

The data were entered into the SPSS version 6.0 data file and statistical analysis was performed using the t test for continuous variables and Chi-square for counts. Results were expressed as mean ±SD or 95% confidence intervals where appropriate. The differences were considered significant when the p level was lower than 0.05.

RESULTS

The characteristics of 404 RA patients are given in Table 1. Of all patients, 83.7% were women on the average 60.4 years old (range, 20 to 87). The average duration of the disease was 12.2 years. Of the whole group of patients, 24% were working people,

Table 1. **Demographic and clinical variables from the survey of RA patients**

Characteristics	Demographic and clinical variables n = 404	Missing data	Population
Age	60.4 (12.7)*		–
Females	338 (83.7%)		52.9%
Disease duration	12.2 (9.5)*		–
Years of education	11.9 (6.3)*		
University education	85 (21%)		13.2%
Employment	97 (24%)		55.4%
Disability	235 (58.2%)		2.67%
NSAIDs	397 (98.3%)		
Corticosteroids	300 (74.3%)		
Intra-articular injections	216 (53.5%)		
DMARDs	346 (85.6%)	7	
Synovectomy	35 (8.7%)		
Prosthesis operations	19 (4.7%)		
RA in the family	131 (32.4%)	207	

* Mean (standard deviation).

21% had university education (the population data show 13.2% having university education) and the average term of study throughout life was 11.9 (6.3) years. As many as 58.2% of the surveyed had a disability grant *versus* the overall rate of the population (disability rate 2.7%) and their functional class was 2.2 (0.7).

NSAIDs were taken practically by all RA patients (98.3%), and most of them (73%) were taking these drugs constantly.

Of RA patients, 74.3% were taking corticosteroids and almost half of them (42%) were taking corticosteroids constantly. The corticosteroid injections into the joints had been performed to 53.5% of the patients in the past. The injections were performed mostly into the knee-joints to 143 (35.4%) patients. The injections were performed 2.7 (2.6) times on the average, though their number ranged from 1 to 20 times for one patient.

The treatment with DMARDs in general (previously or presently) was applied to 85.6% of RA patients, and during the survey the treatment with DMARDs was applied only to 46.3% of the surveyed. As a rule, the second-line drugs were prescribed more frequently to the patients who had been ill for a short period of time. DMARDs were prescribed to 62.9% of those with the disease duration less than 4 years and considerably less often to those who had been ill for more than 10 years (37.1%, p = 0.00) (Table 2). The most commonly prescribed drug of this group in the past and at the time of the survey was sulfasalazine (Table 3). It was prescribed to 47% of the patients, and at the time of the survey 19.6% were taking it. Methotrexate (MTX) is the second by frequency drug taken currently. During the survey 13.6% of the patients were taking it, altogether 34.2% of RA patients have received MTX. Antimalarials earlier were quite common in rheumatology practice (up to 40.6% of the patients have been treated this way), but only 5% of RA patients received these preparations at the time of the survey. Azathioprine was prescribed to 23.5%, and currently 11.9% of the patients are taking it. 25.7% of the patients were treated with gold preparations, 2.7% – with cyclophosphamide, 1.7% – penicillamine and only 3 patients (0.7%) were administered cyclosporine.

The treatment duration with DMARDs was as long as 20 months for antimalarials and as short as 6 months on the average for gold preparations (Figure). Seventeen months is the average period of treatment with sulfasalazine, even shorter is the period of time for treatment with methotrexate (14 months), 11 months with penicillamine, and 10 months with azathioprine. The reasons for the termination of the treatment with DMARDs generally remained unknown for all types of drugs. Only half of all the surveyed patients could precisely state the reason of termination of this or that drug. The side effects of the drugs were mentioned more frequently in comparison to the other known reasons; 33.6% of those ever taking gold pointed out this reason for the termination of treatment. Of those who had been treated with antimalarial drugs, 11.0% mentioned the inefficiency as the most common reason. Surgery of joints was applied to 13.4% of the patients: synovectomy to 8.7%, prosthesis operations to 4.7%. Prosthesis operations were performed on the average after 16 years

Table 2. **Proportion of patients with DMARDs currently in relation to disease duration**

Disease duration	Total number of patients	Patients using DMARDs		
		Number	Percentage	95% CI, lower and upper limits
Up to 4 years	97	61	62.9	52.45–72.32
4–10 years	137	63	46.0	37.53–54.70
Over 10 years	170	63	37.1	29.92–44.80
Total	404	187	46.3	41.37–51.30

Table 3. **Treatment with DMARDs**

Preparations	Currently used, %	95% CI, lower and upper limits	Ever used, %	95% CI, lower and upper limits	P, chi test
Antimalarial preparations	5.0	3.17–7.73	40.6	35.80–45.58	<0.01
Gold preparations			25.7	21.57–30.31	<0.01
Penicillamine			1.7	0.74–3.65	<0.01
Methotrexate	13.6	10.49–17.42	34.2	29.62–39.08	<0.01
Azathioprine	11.9	8.99–15.56	23.5	19.51–28.00	<0.01
Cyclophosphamide	0.5	0.09–1.98	2.7	1.42–4.94	<0.05
Sulfasalazine	19.6	15.91–23.88	47	42.06–52.00	<0.01
Cyclosporine			0.7	0.17–2.28	<0.01

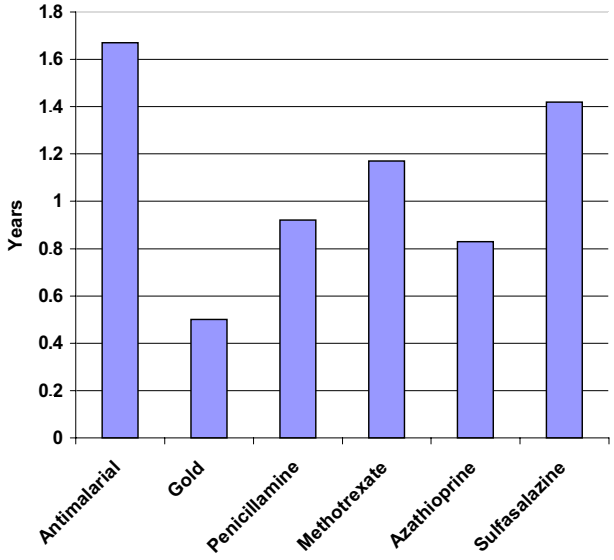

Figure. Average duration of the treatment

from the beginning of the disease, mostly on the knee-joint.

DISCUSSION

According to the data of Vilnius RA Register, NSAIDs were taken by 98.3% and corticosteroids by 74.3% of RA patients. The treatment with DMARDs in general (previously or presently) was applied to 85.6%. There are mainly two rheumatological databases in Europe – Oslo (Norway) and German, which were developed and designed to measure the impact of RA, including the treatment analysis. The data of Oslo RA Register are very similar: almost all the patients (99%) were taking NSAIDs (13–16). Analyzing the data of the German rheumatological database of 1998 which includes the clinical and survey data on 12,992 RA patients, we found that only 59% of RA patients had been ever taking NSAIDs in that study (17, 18).

Corticosteroids were prescribed more often in Vilnius (74.3%) than in other European countries. According to the data of Oslo RA Register, corticosteroids were taken by 60% of the patients. These data are similar to those in Germany (56%): rheumatologists prescribe small doses of corticosteroids (≤7.5 mg/d) 5 times more often than bigger doses. Bigger doses (>7.5 mg/d) were prescribed only to 10% of the patients. According to the data of Californian long-term RA studies, prednisone was prescribed to 54% of RA patients (19). In Vilnius, intraarticular injections of corticosteroids were performed to half and in Germany only to 7% of RA patients.

DMARDs in Vilnius were prescribed as frequently as in other countries: in Vilnius 85.6%, in Oslo 85%, in Germany 88%, a little more in Sweden – 93% (13–18, 20). In Vilnius, the most commonly prescribed drug of this group in the past and at the time of the survey was sulfasalazine. It was prescribed to 47% of the patients. Methotrexate goes second, though many other countries prefer methotrexate as the first choice drug. MTX is the most popular drug of RA treatment in North America, West Europe and Scandinavia (21–24). This choice is supported by relatively infrequent complications of treatment, rapid manifestations of the effect, convenient schemes of application and the possibility to combine it effectively with other DMARDs (22–27). Though it could be argued if it can totally block RA progression, most researchers think that MTX substantially slows down the progression of the morphological changes. At the time of the survey (1998), in Germany 56% of the respondents were treated with methotrexate, in Sweden (1995) 21%, however, it was still the most commonly prescribed DMARD. The traditions of each country, the activity of the pharmaceutical companies working there, the economical power of the inhabitants – all these factors determine a rather different popularity of one or another DMARD in different countries.

When 4032 American and 950 European (British and Danish) rheumatologists were questioned, European rheumatologists rather than Americans spoke up for sulfasalazine (25). Prescribing combined treatment, most American rheumatologists would recommend to combine methotrexate with hydroxychloroquine, while most European rheumatologists were in favour of methotrexate with sulfasalazine, in Germany, though, the combinations of methotrexate and antimalarial drugs were more common than those of methotrexate and sulfasalazine. In general, in cases of complicated RA forms combined treatment is prescribed more often in the USA (58%) (25, 26) than in Europe (32%).

In Vilnius, antimalarial drugs had been prescribed formerly quite often (40.6%), but at the time of the survey antimalarial drugs were taken by 5% of the patients. In Germany 16% and in Sweden 10% of RA patients receive these drugs. Although in the latest years many more effective anti-rheumatic preparations emerged, antimalarial drugs are still quite widely used as DMARDs that act mildly and cause the least hazard to the patient. Retinopathy is almost the only one serious complication that antimalarial drugs might cause (27). Considering the data of this study, not the treatment complications but rather inefficacy was the reason for disrupting the treatment.

In Vilnius, 11.9% of the surveyed took azathioprine at the time point, in Germany, however, only

3% of the patients took it. Although azathioprine is one of the oldest immune-suppressants used in rheumatology, the researchers still dispute on its anti-rheumatic activity (23–24). Azathioprine is usually chosen when RA visceritis, kidney damage, amyloidosis are evidenced.

According to the data of Vilnius RA Register, antimalarial drugs were taken for the longest period of time – 1.67 years, sulfasalazine 1.42, methotrexate 1.17 years. In the USA, the data on RA patients have been recorded for 14 years (21). The duration of treatment with gold, antimalarial preparations or penicillamine was 2 years on the average or less and with methotrexate 4.25 years.

In Vilnius, the majority of the patients didn't know the reason for the termination of DMARDs. Afterwards the side effects of the drugs were mentioned more frequently in comparison to the other known reasons. In USA, the side effects of the drugs were more common reason for the termination of the treatment than the lack of efficiency, and both were a more seldom observed among those who were taking methotrexate (21). Neither the duration nor the severity of the disease or demographic factors had any influence on the termination of the drug in the USA study. Only in 1% of cases the treatment was terminated because of remission. Five of them were treated with intramuscular gold and one with hydroxychloroquine.

CONCLUSIONS

As a rule, second line drugs were prescribed to the patients who had been ill for a short period of time. Sulfasalazine is the most commonly taken DMARD. The antimalarial drugs are the ones with which the patients are treated for the longest period of time. The reasons for the termination of DMARDs in the majority of cases were unknown; side effects of the drugs were mentioned more frequently in comparison to the other known reasons.

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REUMATOIDINIO ARTRITO GYDYMO ANALIZĖ, PAREMTA VILNIAUS REUMATOIDINIO ARTRITO REGISTRO DUOMENIMIS

Santrauka

Tikslas: išanalizuoti pacientų, sergančių reumatoidiniu artritu, gydymo tendencijas remiantis Vilniaus miesto reumatoidinio artrito (RA) registro duomenimis.

Medžiaga ir metodai. RA sergančiųjų gydymo analizė atlikta naudojant Vilniaus RA registro, įkurto 1998-ųjų pabaigoje ir sudaryto iš 1018 RA pacientų (iš 486 506 suaugusių Vilniaus miesto gyventojų) duomenų. Vilniaus RA registras yra kasmet papildomas naujai susirgusiais ligoniais, patikslinamas mirties ar išvykimo iš miesto atveju. Pacientai įtraukiami į registrą, jei apklausos metu jie atitinka klasifikacinius ACR'88 RA kriterijus (Arnet FC, 1988) ir yra Vilniaus miesto gyventojai. Tyrimas atliktas panaudojant 404 sergančiųjų apklausos duomenis.

Rezultatai. Nesteroidinius vaistus nuo uždegimo (NVNU) vartoja praktiškai visi 98,3% ligonių, nuolat vartojančių yra 73,0%. Beveik pusė (42%) RA sergančiųjų nuolat vartoja peroralinius kortikosteroidus. 53,5% pacientams buvo atliktos gliukokortikoidų injekcijos į sąnarius. Gydymas ligą modifikuojančiais vaistais buvo paskirtas 85,6% RA sergančių ligonių. Apklausos metu baziniais vaistais buvo gydomi 46,3% apklaustųjų. Dažniau šis gydymas buvo skiriamas trumpai sergantiems ligoniams, kai ligos trukmė yra ne ilgesnė kaip 4 metai – 62,9% ir daug rečiau sergantiems ilgiau nei 10 metų – 37,1% (p = 0,00). Dažniausiai vartojamas šios grupės vaistas – sulfasalazinas. Sulfasalaziną yra vartoję 47% RA sergančiųjų. Apklausos metu jį vartojo 19,6% pacientų. Antroje vietoje pagal vartojimo dažnumą šiuo metu yra metotreksatas. Ilgiausiai ligoniai buvo gydomi chinolino grupės vaistais – 20 mėnesių. Gydymo ligą modifikuojančiais vaistais nutraukimo priežastys dažniausiai likdavo nežinomos, antroje vietoje pagal dažnumą buvo minimi pašaliniai vaisto reiškiniai. Sąnarių chirurgija buvo taikyta 13,4% ligonių, iš jų sinovektomija – 8,7%, o sąnarių protezavimo operacijos – 4,7% ligonių. Protezuojama buvo praėjus vidutiniškai 16 metų nuo ligos pradžios, dažniausiai – kelio sąnarys.

Išvados. Ligą modifikuojančius vaistus daug dažniau vartoja trumpai sergantys ligoniai. Dažniausiai vartojamas sulfasalazinas. Ilgiausiai ligoniai gydomi chinolino grupės vaistais. Dauguma ligonių nežino gydymo ligą modifikuojančiais vaistais nutraukimo priežasčių. Iš žinomų nutraukimo priežasčių vyrauja pašaliniai vaisto sukelti reiškiniai.

Raktažodžiai: reumatoidinis artritas, gydymas, ligą modifikuojantys vaistai, RA registras