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Gerontorheumatologic outpatient service

To the Editor:

In western society, the percentage of elderly people in the population has increased dramatically and is likely to increase more in the decades to come. In the year 2000, 13.4% of the general population in The Netherlands was older than 65 years, and this percentage will increase to 23.3% in 2025 (1). The shift toward an older population will place a heavy burden on the health care system, because health problems in the elderly are often complex and expensive to treat. Existing special care for the elderly is most often focused on patients with cognitive problems (2). However, the most frequently reported health problems in the elderly are related to the locomotor system (3,4). Due to a low incidence of rheumatic diseases in an average practice, the general practitioner may have difficulties in diagnosing and treating rheumatic conditions (5). The presented symptoms may be the result of a wide range of endocrine, metabolic, traumatic, and psychological conditions, and the clinical picture of some rheumatologic disorders is different in elderly patients as compared with younger patients (6,7). After proper diagnosis, treatment may be limited in older patients. For instance, older people seem to be more vulnerable to side effects of medication (8) and are often unable to undergo complex treatment due to impaired motor and cognitive function (9). Finally, in elderly patients the ability to cope with health related problems is often impaired by a decrease in informal care and income, an increase in loneliness (6), and higher vulnerability to depression (3). It has been suggested, therefore, that there is a need for specialized services aimed at improving health care for the elderly with rheumatic conditions (9).

At the Sint Maartenskliniek in Nijmegen, The Netherlands, such a specialized service has been introduced: the gerontorheumatologic outpatient service. This service was developed to support the general practitioner in diagnosing and treating elderly patients with locomotor problems. The aim of the service is to prevent unnecessary impairment and disability, preserve independence in activities of daily life, improve mobility, decrease pain, improve care quality, and reduce care quantity. General practitioners refer patients older than 75 years with locomotor problems to the gerontorheumatologic outpatient service. Patients are scheduled for a visit to the rheumatologist and a specialized nurse practitioner. Directly following the dual appointment, the rheumatologist and nurse decide on a course of action. Three actions are possible: no further treatment in the hospital but advice to the general practitioner related to diagnosis and treatment, additional treatment in primary care, and multidisciplinary treatment in the hospital. Patients are informed of the examination findings and treatment options are discussed. The referring general practitioner is informed about the results of the patient examination and treatment advice.

Data from the first 100 patients are reported here. The average age of the patients was 78 years, range 75–91 years. Patients were predominantly female (85%). In the sample, 45% of the patients lived together with their partner, 55% lived alone. Most patients lived independently (86%), whereas 14 patients lived in a senior citizens home.

Table 1 illustrates the complexity of problems in this sample. Multiple diagnoses were observed in most of these elderly patients. A total of 174 rheumatologic diagnoses were set in 100 patients, with more than 1 diagnosis observed in 55 patients. Most predominant was osteoarthritis, which was found in more than half of the patients, often in combination with another diagnosis. Furthermore, there was a high incidence of nonrheumatologic conditions in this population. Only 25 patients were free of nonrheumatologic chronic conditions. In 33 patients, 1 nonrheumatologic condition was found and in 22 patients there were 2. No patients with substantial cognitive functional impairments (for instance as in dementia) were referred to the service. Therefore it is concluded that this new service reached the designated target group: the elderly patient with locomotor problems.

Patient functioning was assessed using the Modified Barthel's Index (MBI) (10). The MBI measures independence of the patient in 15 activities of daily life independent of diagnosis. There was a large variety of functional independence within this group of patients. Complete independence was observed in 33 patients (maximum MBI score). Another 33% showed relatively high independence (MBI scores ranging from 88 to 99 points). Finally, another third of the patients showed marked dependence on a series of activities of daily living (50–87 points).

Additional actions were based on the rheumatologist's and the nurse practitioner's findings in each individual patient. Most patients (n = 59) were referred back to the general practitioner. In these cases, the practitioner received additional diagnosis and treatment advice shortly after the visit to the hospital. An additional 10 patients were referred back to the general practitioner after 1–3 additional visits at the outpatient clinic. The remaining 31 patients received further treatment by the rheumatologist, 19 of them received regular outpatient treatment by the rheumatologist alone. In 12 patients, the problems were deemed serious enough to warrant multidisciplinary treatment, either ambulatory, clinical, or surgical. The rheumatologist prescribed medication for 82 patients. Physical therapy was prescribed for 17 patients and occupational therapy for 3.

Patients were contacted again by mail 6 months after the gerontorheumatologic service was ended to participate in a patient evaluation. Of the initial 100 patients, 81 completed and returned the questionnaire. Patients were very

Table 1. Frequencies of rheumatologic diagnoses and comorbidity (n = 100)

Rheumatologic	No.	Nonrheumatologic	No.
Osteoarthritis	60	Cardiovascular disease	36
Spondylosis	39	Hypertension	29
Crystal-induced arthritis	15	Diabetes mellitus	20
Osteoporosis	14	Cerebrovascular disease	14
Rheumatoid arthritis	13	Gastrointestinal disease	14
Arthritis, other	12	Pulmonary COPD*	11
Shoulder problems	10	Hormonal disease	9
Soft-tissue disorders	5	Neurologic disorder	3
Polymyalgia rheumatica	4	Others	4
Others	2		

* COPD = chronic obstructive pulmonary disease.

positive about the content of the service. Most patients (86%) indicated that they had used the information and advice given during the gerontorheumatologic service, and 75% indicated that the service had given them new information. Most patients (89%) would recommend the service to other patients of their age with similar problems, and 92% of the patients gave an overall positive evaluation. Similar levels of patient satisfaction are very common in the evaluation of treatment services. Therefore, the evaluation by the general practitioner is a more reliable measure. In The Netherlands, general practitioners are in close contact with the patient and are well aware of the patient's situation. All 77 referring practitioners were contacted by mail 6 months after they referred a patient to the gerontorheumatologic service. A short questionnaire was sent by which they could evaluate the content of the service. Of these 77 practitioners, 53 returned the mailed questionnaire (response rate 69%). Of the responding general practitioners, 83% thought that the additional diagnostics given by the rheumatologist were relevant in treating the patient. They felt confident that the service had a positive effect on the patient (82%) by reducing pain, improving activities of daily life, or improving mobility. Consequently, 89% of the referring practitioners evaluated the service as an important and positive initiative, and would recommend it to their colleagues.

These preliminary results underline the importance of special care for the elderly with locomotor problems. The high incidence of multiple diagnoses underlines the complexity of physical problems in this sample. Given the complex diagnostics, it is remarkable that a large number of patients are able to maintain their independence at an advanced age. However, a small group of patients in this sample experience severe dependence on others in their daily activities. The rheumatologist was able to give the general practitioner useful advise regarding this group of patients. The general practitioners who returned the questionnaire gave a positive evaluation of the gerontorheumatologic outpatient service. The new service therefore reached its goal, because it helped the general practitioner diagnose and treat elderly patients with locomotor problems.

More studies are needed to determine the usefulness and effectiveness of this new service. For instance, no attempt was made to determine the patients' compliance with the advice, or whether the advice had the desired effects. Furthermore, additional information on the patients' social and psychological function should be gathered, as well as information about the informal care and income of the patient. Nonetheless, the service is evaluated as positive by both the patient and the referring general practitioner. These findings suggest that the service may help solve the problems of an aging society. Many patients can be treated very well, and the little effort invested in this new service might help the patient maintain independence.

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Anti–tumor necrosis factor α switching in rheumatoid arthritis and juvenile chronic arthritis

To the Editor:

Over the past few years, tumor necrosis factor α (TNFα)–blocking agents have been increasingly used in the treatment of severe refractory rheumatoid arthritis (RA) (1–3) and juvenile RA (JRA) (4). The 2 most widely used approaches to inhibiting the action of TNFα have thus far been the administration of soluble TNF receptor (etanercept) or anti-TNFα chimeric antibodies (infliximab). Several trials have shown that both of these biologic agents are very effective in reducing the signs and symptoms of joint inflammation, inhibiting radiographic progression, combatting disability, and improving the quality of life of patients with RA or JRA (5,6). However, some patients have to discontinue treatment because of adverse events or a lack of efficacy (5,6), and, because most of them have been previously treated with all of the nonbiologic disease-modifying antirheumatic drugs (DMARDs), it may be difficult to choose an alternative therapy. In a open-label pilot study, we investigated whether switching from one to the other anti-TNFα agent is a safe and effective procedure in such patients.

The study group included 15 patients (14 women and 1 man; mean ± SD age 46.4 ± 6.92 years). Eight of these patients had RA, 7 had JRA, and all of them had discontinued infliximab or etanercept therapy because of a lack of efficacy or adverse events. None of the patients had contraindications to the use of anti-TNFα agents, and all gave their informed consent. All patients had severe, longstanding, active disease (mean ± SD disease duration 13.2 ± 2.07 years, and a Disease Activity Score in 28 joints [DAS28] >3.7). In all patients disease was refractory to treatment with traditional DMARDs.

Fourteen of the 15 patients were being treated with infliximab (3 intravenous infusions of 3 mg/kg every 45 days) and low-dose methotrexate (median dosage 12.5 mg/week), which was discontinued after a mean (± SD) period of 10.3 ± 2.03 months because of a lack of efficacy (according to the American College of Rheumatology [ACR] 20% improvement criteria) in 8 patients or adverse events (2 cases of hypotension, 1 case of angioedema, 1 case of urticaria, and 2 cases of respiratory distress). The only patient being treated with etanercept (25 mg subcutaneously twice weekly) discontinued the therapy because of a lack of efficacy after 6 months of treatment.

Patients were switched to the alternative treatment 4 weeks after the discontinuation of the previously administered anti-TNFα drug and were then monitored for tolerance and efficacy once a month for 6 months. The efficacy parameters used in this study were the number of tender and swollen joints (28-joint count), pain measured with a visual analog scale (VAS), a VAS general health assessment, the first-hour erythrocyte sedimentation rate, the levels of C-reactive protein and hemoglobin, the DAS28, and the disability index of the Health Assessment Questionnaire. Safety and tolerability was monitored by recording all adverse events and performing a thorough physical examination and standard laboratory investigations at each control visit.

Twelve of the 14 patients treated with etanercept completed the 6-month study period. The other 2 had to discontinue therapy for the same reason they had stopped their previous treatment with infliximab: one patient discontinued treatment after 5 months because of a lack of

Table 1. Clinical and laboratory parameters at baseline and after 6 months in patients with RA or JRA*

	Baseline				6 months			
	Mean ± SD		Median (range)		Mean ± SD		Median (range)†	
	RA	JRA	RA	JRA	RA	JRA	RA	JRA
ESR, mm/hour	50.5 ± 27.7	55.4 ± 22.9	41 (21–100)	40 (25–100)	34 ± 22.1	32 ± 20.1	32 (7–77)	31 (6–81)
CRP, mg/dl	2.57 ± 2.6	3.12 ± 2.8	1.8 (0.3–9.5)	1.7 (0.4–9.2)	1.1 ± 0.7	1.2 ± 0.6	1.25 (0.1–2.8)	1.3 (0.1–2.9)
Hemoglobin, gm/dl	11.5 ± 1.0	11.4 ± 1.2	11.4 (10.3–13)	11 (10.7–13)	12.3 ± 1.0	12.6 ± 1.3	12.3 (11–14)	12 (11.5–14)
Tender joint count	13.6 ± 7.7	11.7 ± 6.9	11 (5–26)	11.5 (6–25)	6.4 ± 5.5	6.1 ± 5.2	5 (0–18)	5.5 (0–15)
Swollen joint count	12.1 ± 5.5	12.3 ± 5.4	13.5 (5–20)	13.5 (4–22)	7.1 ± 5.3	6.9 ± 5.1	5 (1–18)	5 (0–16)
Pain VAS	61.3 ± 25.9	65.6 ± 22.8	62 (16–98)	64 (20–96)	40.1 ± 21.2	40 ± 21.8	44 (8–64)	42 (8–61)
GH VAS	62.8 ± 21.3	66.4 ± 20.3	62.5 (20–90)	62.5 (25–90)	35.8 ± 18.9	33.8 ± 17.9	32.5 (9–65)	30.5 (8–62)
DAS28	6.02 ± 1.2	6.1 ± 1.1	6.1 (4.4–7.9)	6 (4.3–7.8)	4.6 ± 1.4	4.5 ± 1.5	4.7 (2.7–6.6)	4.6 (2.6–6.5)
HAQ	1.85 ± 0.5	1.88 ± 0.6	2 (0.37–2.5)	2 (0.4–2.5)	1.51 ± 0.6	1.47 ± 0.7	1.7 (0.2–2.2)	1.6 (0.2–2.4)

* RA = rheumatoid arthritis; JRA = juvenile rheumatoid arthritis; ESR = erythrocyte sedimentation rate; CRP = C-reactive protein; VAS = visual analog scale; GH = general health; DAS28 = Disease Activity Score in 28 joints; HAQ = Health Assessment Questionnaire.
† $P < 0.05$, RA versus JRA, by Wilcoxon's rank test for all comparisons.

efficacy, and the other discontinued treatment after 3 months because of the recurrence of the same adverse event (angioedema). During the 6 months of therapy, diffuse urticaria developed in 2 patients, which was easily controlled by antihistamine treatment and did not prevent them from continuing etanercept. The only patient who switched to infliximab completed the 6-month therapy without experiencing any adverse event. After 6 months of therapy, the median values of the efficacy variables measured in all patients of were significantly better than those recorded at baseline (Table 1). By month 6, 13 of the 15 patients were responders according to the ACR 20% improvement criteria.

The results of this study seem to indicate that, as previously reported by other authors (7,8), switching from one anti-TNFα treatment to the other may be successful in patients with severe and active RA or JRA who fail to respond to all of the nonbiologic DMARDs. Only 2 of our 15 patients failed therapy with both drugs (curiously enough, for the same reason).

In conclusion, our results suggest that, if the first administered anti-TNFα drug (infliximab or etanercept) has to be discontinued because of a lack of efficacy or an adverse event, switching to the other anti-TNFα is likely to be safe and effective.

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Results from an open-label extension study of etanercept in ankylosing spondylitis

To the Editor:

The efficacy and safety of etanercept in the treatment of ankylosing spondylitis (AS) in a 4-month randomized, double-blind, placebo-controlled trial has been previously described by our group (1). After participation in the initial 4-month trial, patients could enroll in a 6-month open-label extension period. We now provide the results of the open-label study as well as a description of the effects of a total of 10 months of etanercept treatment in patients with AS.

Thirty-eight of the original 40 patients in the study enrolled in the 6-month extension trial and received open-label etanercept (Enbrel; Immunex, Seattle, WA) at a dose of 25 mg subcutaneously twice weekly; 36 patients completed the open-label extension. Patients in the original etanercept group continued to demonstrate sustained benefit with continued therapy, and patients in the original placebo group achieved similar improvements once they began receiving etanercept. After 4 months in the original study, 14 of 19 etanercept patients (74%) had achieved an Assessments in Ankylosing Spondylitis 20% response (ASAS20) (2), and after an additional 6 months of etanercept, 16 of 17 patients (94%) had achieved this end point. In comparison, 5 of 19 original placebo patients (26%) achieved the ASAS20 at the end of the 4-month study, but after 6 months of open-label etanercept, 16 of 19 patients (84%) achieved the end point.

Additionally, with extended therapy with etanercept, many patients achieved the more stringent ASAS50 and ASAS70 responses, representing 50% and 70% improvements from baseline, respectively. At the end of the 10-month study, a total of 29 of 36 patients (81%) achieved the ASAS50, and 15 of 36 (42%) achieved the ASAS70. Of particular note, at the end of the original 4-month study, only 3 of 19 patients (16%) in the original placebo group achieved the ASAS50, and only 2 of 19 (11%) achieved the ASAS70. After 6 months of open-label etanercept, however, 16 of 19 patients (84%) achieved the ASAS50, and 9 of 19 patients (47%) achieved the ASAS70.

Five primary outcome measures (duration of morning stiffness, nocturnal spinal pain, the Bath Ankylosing Spondylitis Functional Index [3], patient global assessment, and swollen joint count) were assessed independently over the 10-month period. Mean values of these

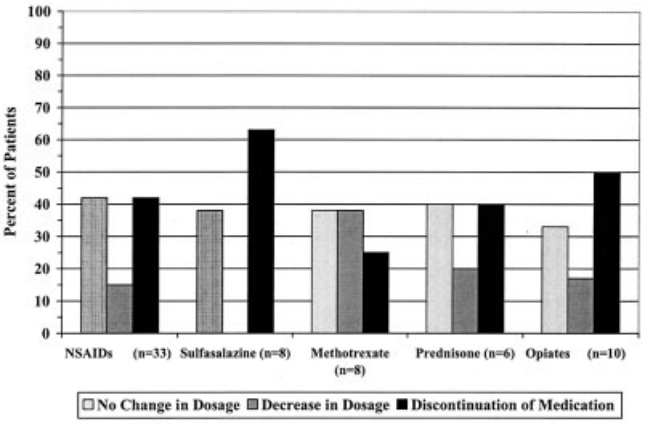

Figure 1. Medication changes during treatment with etanercept. NSAIDS = nonsteroidal antiinflammatory drugs.

measures were similar at baseline in both of the original treatment groups. At 10 months, patients in both treatment groups showed significant percent improvements from baseline in the primary outcome measures, indicating that etanercept has a sustained effect on these aspects of AS (data not shown).

Measures of spinal mobility (chest expansion, modified Schober's test, and occiput-to-wall measurement) also showed significant improvement with etanercept therapy. Of the patients who received placebo in the original 4-month study period and received etanercept during the 6-month extension, the mean percent improvement from baseline at 10 months was 48.8% for the chest expansion measurement, 7.8% for the modified Schober's test, and 24.8% for the occiput-to-wall measurement. In the group that received etanercept throughout both periods, the mean percent improvement from baseline was 59.6% for chest expansion, 26.2% for the modified Schober's test, and the 48.1% for the occiput-to-wall measurement. The 3-fold improvement in the modified Schober's test in the group that received continuous etanercept treatment suggests that some aspects of spinal mobility in AS patients may benefit from a longer etanercept treatment period. Recent studies have shown significant improvement in a composite measure of spinal mobility (Bath Ankylosing Spondylitis Metrology Index) (4) with infliximab (5) and pamidronate (6). Additionally, spinal mobility improvements have been reported in a phase III clinical trial with etanercept (7).

Etanercept continued to be well tolerated during the 6-month extension of the study. Adverse events occurred with similar frequencies during the blinded and open-label phases of the trial. There were no deaths, no serious adverse events or infections, and no safety-related discontinuations during the extension period. We observed no cases of tuberculosis or malignancies.

Of interest, during the controlled phase of the study, patients could continue preexisting AS therapies such as nonsteroidal antiinflammatory drugs (NSAIDs), methotrexate (≤20 mg/week), sulfasalazine (≤3 gm/day), and/or oral corticosteroids (≤10 mg/day). During the open-label extension, thus, they could modify their treatment regimens. At baseline of the original study, 84% of patients were receiving NSAIDs, 39% were receiving disease-modifying antirheumatic drugs (DMARDs), and 16% were being treated with corticosteroids. Approximately 40% of patients were receiving 2 or more medications for treatment of their AS. By the end of the open-label extension, 66% of all patients discontinued or decreased at least one of their AS therapies (Figure 1). A total of 14 patients (42%) discontinued NSAID therapy, and 5 patients (15%) decreased the dosage. One patient, who had not been receiving an NSAID, added a selective cyclooxygenase-2 inhibitor after discontinuing methotrexate and prednisone. A total of 8 patients (53%) discontinued at least one DMARD by the end of the open-label study: 5 patients (63%) discontinued sulfasalazine, 2 patients (25%) discontinued methotrexate, and 3 patients (38%) decreased the dosage of methotrexate. Corticosteroid use also was decreased or discontinued.

Etanercept represents an important advancement in the treatment of AS. In addition to successfully modifying the characteristic axial manifestations of disease, etanercept appears to be well tolerated. More extended observations will be important in assessing the long-term safety and impact of etanercept on disease progression.

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Erratum

In the article by Mayer et al published in the December 2003 issue of *Arthritis Care & Research* (pp 759–65), it says, "Six states in the United States have no pediatric rheumatologist practicing within their borders . . ." The sentence (page 761) should have read "Ten states in the United States have no pediatric rheumatologist practicing within their borders: Arkansas, Idaho, Iowa, Maine, New Hampshire, North Dakota, Nevada, South Dakota, West Virginia, and Wyoming.

We regret the error.