Collection of data terminated at the end of the year 2000. Although, as this abstract is prepared, some data sets are still awaited, it is likely that analysis will be based on data from 312 patients judged to have polymyalgia rheumatica recruited from 13 centres.

The vast majority of these patients, judged by a consensus of experts to have polymyalgia rheumatica, have provided a database for comparison of the various diagnostic criteria sets.

On the basis of this, optimum European diagnostic criteria will be proposed. Investigators are encouraged to use this in their research on polymyalgia rheumatica to further substantiate their reliability. A handout listing the new criteria will be available at the time of the presentation.

REFERENCES

- 1 Bird HA, *et al.* *Ann Rheum Dis.* 1979;**38**:434–9
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SP0054 POLYMYALGIA RHEUMATICA REMISSION CRITERIA

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Polymyalgia rheumatica (PMR) is not a benign disease. Additional morbidity may arise from prolonged administration of high doses of corticosteroids. No stringent response criteria have been established yet, however, they obviously seem to be of great importance for the quality of patient care and to compare alternative treatment modalities against the golden standard of steroid treatment as steroid sparing medications would be most desirable in PMR.

Patients and methods Patients from several European countries were enrolled into a study to validate existing diagnostic criteria for PMR as well as into the remission criteria study. Serological findings (ESR, CRP, haemoglobin, serum iron and alpha2-globulin) and clinical features (VAS pain, VAS physicians assessment, morning stiffness, elevation of upper limbs, myalgia, tenderness on pressure of upper/lower limbs, response time after initiation of steroids, head aches, swelling or tenderness of the temporal artery and masseter muscle claudication) were chosen for the characterisation of disease activity. After the initial examination patients were seen at week 1, 4, 8, 16, 24 and 32, study end-point was at week 48. Starting dose and reduction of corticosteroids as well as co-medication was at the discretion of the local investigator. Patients found to have a disease other than PMR will be excluded from final analysis in the response criteria study.

Results As expected most of the patients responded well and quickly to steroid treatment. The results concerning the single response parameters will be given on date. Consisting of those criteria performing best a response score should be proposed. The efficacy of treatment may thus easily be reflected by a single figure.

SP0055 POLYMYALGIA RHEUMATICA NEW TREATMENT (NEW STEROID SPARING AGENTS)

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Polymyalgia rheumatica (PMR) responds well to glucocorticoids such as prednisone when given in small to medium-sized doses. But because the condition tends to persist for months or even years, adverse effects develop in most patients (Gabriel, *et al.* *Arthritis Rheum* 1997;**40**:1873). A variety of steroid sparing drugs have been tried. One NSAID, Tenidap, showed steroid sparing efficacy but also relatively frequent adverse effects. The new Cox-2 inhibitor drugs have not been studied adequately in PMR to determine if they have a role in certain cases.

Experience with cytotoxic drugs has been mainly in cases of giant cell arteritis (GCA), some of whom also had PMR. Even in GCA, cytotoxic investigations have been limited. Because of the close link between GCA and PMR it would be presumed that drugs useful for GCA would also be effective in PMR. Methotrexate has been studied most. Two recent randomised, double-blind, placebo-controlled studies using methotrexate as a steroid sparing agent are the best work on this question to date, but gave different results. In one (Jover, *et al.* *Ann Intern Med* 2001;**134**:106), 33 patients completed the trial. 18 patients were given prednisone plus placebo, and 15 were given daily prednisone plus 10 mg methotrexate per week. All were followed for 24 months. The group receiving methotrexate with prednisone experienced fewer relapses ($p = 0.02$) and used significantly less prednisone ($p = 0.004$) over the study period. The second study (Hoffman, *et al.* In press) was also a prospective randomised double-blind study. 98 patients were enrolled. 51 received methotrexate (mean dose 15 mg per wk) plus prednisone, and 47 received placebo and prednisone. The results showed that the methotrexate group was not different from the placebo group regarding outcome and prednisone dose. The reasons for the differences between these studies is not completely clear but will be discussed. Thus, at this time there are no steroid sparing drugs that can be relied on for PMR. At this time in the practice setting we would recommend a trial of methotrexate only in patients who at very high risk of developing steroid side effects. Additional investigations with this drug and others is needed.

Clinical epidemiology in practice – Thursday 14 June, 16.00-17.30/Meeting Hall IV

SP0056 MEASUREMENT ISSUES

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In a recent European survey of outcome measures for rheumatoid arthritis over 60 different instruments were found to be in use. For low back pain, over 100 different instruments were found to be in use. If, for example, measuring disability is considered important, what are the characteristics of a good measure of disability? How do we choose between competing instruments?

Recent advances in our understanding of outcome measurement have identified a number of fundamental criteria that should be met, prior to more established tests of reliability, validity and responsiveness. The two most important characteristics are unidimensionality and absence of Differential Item Functioning (DIF).

The ICIDH helps us to think conceptually about outcomes, and contributes to measurement by identifying unidimensional