VIEWPOINT

A need for greater reporting of socioeconomic status and race in clinical trials

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Comprehensive data about new treatments for rheumatoid arthritis (RA), including their potential for disease remission, efficacy, and safety, are derived from clinical research. Often these studies can significantly influence management strategies for patients with RA. Virtually all recent studies on RA report disease characteristics relevant to outcome. Factors such as the presence of rheumatoid factor, the number of tender and swollen joints, measurements of acute phase reactants, the presence of radiographic erosions, and prior treatments with disease modifying antirheumatic drugs define the severity of disease, and also, the potential for responses to treatments. The age and sex of the study population are also reported in every study, although their effect on disease outcome is less clear.

However, many clinical studies, including some landmark studies that have dramatically shaped our approach to RA, fail to report other key demographic information. For example, race and socioeconomic status (SES), two potentially critical factors affecting the outcome of patients with RA, are seldom reported in publications (table 1).[1–17] A number of studies have demonstrated that disease outcome in RA correlates inversely and strongly with SES and education.[18–20] Although the data on RA are limited, studies in systemic lupus erythematosus and in non-rheumatological conditions have shown that race can be associated with worse disease prognosis, a more aggressive disease, and a greater functional decline.[21–25] Furthermore, race can influence the efficacy profile of various therapeutic agents.[26–29] Some of the hypotheses to explain these racial differences in the prevalence of disease and the response to treatment have included genetic polymorphisms, differences in SES, and disparities in healthcare use. A better understanding of the role of race on treatment modalities will require inclusion and reporting of race in clinical studies along with subgroup analysis by race.

A heterogeneous study group that reflects the general population with RA is also important for the generalisability of clinical studies. A survey of some recently published clinical trials illustrates that, in general, minorities may be underrepresented in RA therapeutic trials (table 1). Interestingly, it has been suggested that minority patients may be less willing to participate in clinical studies owing to factors such as distrust of physicians/clinical studies, insufficient knowledge about continuing trials, and lower expectations from clinical trials.[30–34]

In many cases, the racial composition, SES, and education may be collected but not be presented in many pivotal trials in rheumatology. Self report of race, SES, and education is inexact but can be easily performed and has been used routinely in many studies. Despite the inexactness inherent in the process, significant correlations have been noted between self reported race, ethnicity, and disease outcome.[35]

Table 1 Demographic reporting of the study group in recent RA studies

Agent [reference]	Study group	Racial composition	SES*	Education
Rituximab[1]	22	Not reported	Not reported	Not reported
CTLA-4Ig[2]	214	White 194 (91%) Black 9 (4%) Other 11 (5%)	Not reported	Not reported
Etanercept[3]	628	White 576 (92%) Black 18 (3%) Hispanic 15 (2%) Asian 12 (2%) Other 7 (1%)	Not reported	Not reported
SSZ+HCQ+MTX[4]	102	Not reported	Not reported	Not reported
Leflunomide+MTX[5]	263	White 234 (89%) Black 15 (6%) Asian 8 (3%) Other 6 (2%)	Not reported	Not reported
CSA+MTX[6]	148	White 137 (93%) Asian 11 (7%)	Not reported	Not reported
SSZ+MTX+prednisone[7]	155	Not reported	Not reported	Not reported
SSZ+HCQ+MTX[8]	195	Not reported	Not reported	Not reported
Prednisone[9]	128	Not reported	Not reported	Not reported
MTX[10]	123	Not reported	Not reported	Not reported
Leflunomide[11]	482	Not reported	Not reported	Not reported
Leflunomide[12]	358	Not reported	Not reported	Not reported
MTX+leflunomide[13]	999	Not reported	Not reported	Not reported
Infliximab[14]	428	White 389 (91%)	Not reported	Not reported
Etanercept+MTX[15]	89	White 70 (79%)	Not reported	Not reported
Etanercept[16]	633	White 544 (86%)	Not reported	Not reported
Adalimumab[17]	271	Not reported	Not reported	Not reported

SES, socioeconomic status; SSZ, sulfasalazine; MTX, methotrexate; HCQ, hydroxychloroquine; CSA, ciclosporin.

Greater availability of this information, either in the publication or on line, will improve our understanding of the safety and efficacy of various therapeutic agents. Also, inclusion of racially and economically heterogeneous populations of patients with RA will increase the external validity of the trial results.

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