New issues in tuberculosis

We read with interest the recent article by Kaufmann, who reported new issues in the epidemiology and treatment of tuberculosis. Dr Kaufmann pointed out that tuberculosis remains a significant health threat in the new European Union member states, in contrast with the “old” EU member states, in which the incidence of this disease is decreasing. Accordingly, he reported the incidence for Slovenia as 20/100 000.

Slovenia as above 20/100 000.
The incidence of this disease is decreasing.

It is important to clarify that the mentioned incidence was last reported in Slovenia in 1999. Since 1995 tuberculosis in Slovenia has been decreasing constantly, reaching an incidence of 17.5/100 000 in 2002.1 (Data also available on website http://www.eurotb.org, accessed 24 February 2005.) The preliminary data of the central registry for tuberculosis in Slovenia have shown a further decrease for 2003, with an incidence of 14.7/100 000 (personal report).

The importance of the omitted information is not only academic. Fictitious higher incidences of tuberculosis misrepresent the risk of this disease in Slovenian patients treated with biological drugs, which could be important in multicentre clinical studies. Furthermore, we would like to mention that the incidence of tuberculosis in patients treated with biological agents in Slovenia is very low. This treatment is centrally indicated and evaluated. We have confirmed only one case of tuberculosis among 200 patients receiving biological agents (anakinra, infliximab, etanercept).

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References


Authors’ reply

I read with great interest the comments about the decreasing incidence of tuberculosis rates in Slovenia. As is stated correctly, the incidence of tuberculosis in Slovenia is now below 20/100 000. Indeed, fig 1 of our report shows the correct incidence rate and the text stating incidence “above 20/100 000” for Slovenia and Slovakia should read “above 15/100 000”. Data for 2002 provided by the most respected organisation, the World Health Organisation, were used for comparison of tuberculosis incidences in different EU member states.

I am pleased to witness a constant decrease in the incidence of tuberculosis in Slovenia (and other EU member states), which may have reached less than 15/100 000 in 2003.

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Disparities in health according to socioeconomic status

The viewpoint expressed by Lee and Kavanaugh1 is of great interest, and may even underestimate the potential importance of data concerning socioeconomic status and race in clinical trials. In one study low formal education level was associated significantly with higher joint counts, erythrocyte sedimentation rate, and patient questionnaire responses.2 In another study, formal education was a more important identifier of poor physical function and high pain scores than age or duration of disease in patients with rheumatoid arthritis, scleroderma, systemic lupus erythematosus, fibromyalgia, and osteoarthritis.3 In the B-HAT study, education level was as prognostic of outcome 3 years after a myocardial infarction, whether patients were randomised to a β blocker, propranolol, or placebo.4

Many physicians continue to believe that the primary reason for associations of low socioeconomic status and poor health is limited access to medical care.5 One explanation is that the classical “biomedical model”6 suggests that disease outcome and health in general is determined largely, if not entirely, by health professionals with minimal contribution from patients. That certainly applies in acute care hospitals, the setting of most medical education and research. In chronic diseases, however, all experienced clinicians recognise that patient actions, attitudes, and behaviour contribute importantly to outcomes—the same physician and treatment will lead to very different results in different patients over long periods. We have suggested that low socioeconomic status serves primarily as a marker to identify patient determined variables in health status rather than limited access to care.7 8 The prevalence of most chronic diseases is higher in people of low socioeconomic status in most Western countries.8 Disparities have widened in recent years in the United Kingdom,9 the Netherlands,10 and the United States,11 despite extensive programmes to reduce these. Then and other data appear explicable only to a small extent on the basis of limited access to medical services.

Finally, the higher prevalence of most diseases in people of low socioeconomic status may be particularly relevant in rheumatic diseases, in which comorbidities are associated with poor outcomes such as premature mortality in rheumatoid arthritis.12 13 We hope that the report of Lee and Kavanaugh will lead to more interest in socioeconomic status and race as important variables in clinical trials.

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References


Authors’ reply

We agree with the comments of Professor Pincus, and appreciate his interest. His points expand upon and agree with our own, very nicely we believe, and we support his remarks.

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Frozen shoulder

The study by Buchbinder et al1 suffers from a major drawback to any study dealing with frozen shoulder when the pathophysiology

References


has passed the acute phase. In their study the mean duration of symptoms was 25.5 weeks in the active group with a standard deviation of 13.3 weeks, the mean therefore being approximately 6 months. This is well over the time course one would expect in the inflammatory phase of frozen shoulder, and therefore it is not surprising that prednisolone provided some benefit. I suspect the benefit provided is related to improvement in myalgia and well being that occurred with the prescription of prednisolone, but which was quickly lost when prednisolone was reduced or stopped.

Although the authors quote a study co-authored by Buchbinder on a standardised protocol for the measurement of shoulder movement,1 I have concerns that the definition of frozen shoulder, as restricted passive movement by <30° in two or more planes measured at the onset of pain with a gravity inclinometer, may not be appropriate, given that frozen shoulder restricts all movements. There may also be other diseases present. In particular, it would be prudent to consider magnetic resonance imaging scans of the shoulder to confirm the degree, or not, of the adhesions within the shoulder capsule, and also to identify other subtle changes which may not be clinically apparent, such as rotator cuff tears unidentified on ultrasound.

The study, therefore, provides no insight or treatment options for prednisolone in frozen shoulder. We failed to recruit patients into the classical acute phase of a frozen shoulder within the first several months. Until such treatment is examined in an appropriate clinical trial, this study by Buchbinder provides no further evidence of the usefulness or otherwise of prednisolone in frozen shoulder. The study, not surprisingly, failed to show any long-lasting benefit of prednisolone because the shoulder, by its natural history, had entered the stiff phase.

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References


Authors’ reply

We thank Dr Champion for his interest and observations about our trial. Our study clearly demonstrated a significant short term benefit of prednisolone in all outcomes measured at 3 weeks, including pain, disability, range of active motion, and participant rated improvement. Similarly, at 6 weeks the analysis still favoured the prednisolone group for most outcomes measured. Therefore Dr Champion’s concern that we may have missed an effect of prednisolone because we did not recruit participants early enough to capture the full course of their illness is unfounded. Furthermore, all participants in the study had significant night pain at baseline (mean (SD) scores 7.5 (2.3) and 6.8 (2.1) in the prednisolone and placebo groups, respectively), generally indicative of acute symptoms and therefore likely to be responsive to steroids.

He highlights, though, an important concern for researchers who wish to study people in the early phase of a self limiting condition such as adhesive capsulitis when there may be delays in both seeking medical care and specialist advice. As outlined in our discussion, various strategies were used to recruit patients early in the course of the condition, including fast track referral.1 Previous trials of both prednisolone and intra-articular steroids have included participants with a similar duration of symptoms,2–4 suggesting that the difficulties of early recruitment are universal.

We agree with Dr Champion that patients with frozen shoulder typically exhibit global restriction of both active and passive glenohumeral movements. Our inclusion criteria specifically included a requirement that there be restriction of passive motion of greater than 30° in two or more planes of movement. This was derived from a systematic review of previous inclusion criteria used in trials of adhesive capsulitis.1 In general, the diagnosis of adhesive capsulitis is easily made by clinical assessment alone. Although it would have been of interest to perform magnetic resonance imaging (MRI) on all patients in this trial, this was not essential to our purpose. We have previously reported the variable presence of enhancing fibrovascular scar tissue in the rotator cuff interval, soft tissue thickening around the biceps anchor, and thickening of the axillary pouch in patients with adhesive capsulitis confirmed at surgery.6 However, the utility of MRI for discriminating adhesive capsulitis from other causes of shoulder pain is currently unknown and further studies are needed.

We stand by our conclusion that a short course of prednisolone for adhesive capsulitis is highly efficacious in the short term. Further research should be directed towards determining ways of prolonging its effect by either lengthening the duration of treatment and/or tapering the dose (without concomitantly increasing the risk of toxicity), and/or considering combination or sequential treatment for adhesive capsulitis.

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References


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Further details can be obtained from: Miss Lisa McClair, ARC Epidemiology Unit, Stopford Building, University of Manchester, Oxford Road, Manchester, M13 9PT, UK. Tel: (0) 161 275 5993, Fax: (0) 161 275 5043. Email: Lisa.McClair@manchester.ac.uk.
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