ARTICLE IN PRESS

+ MODEL

Respiratory Medicine (2015) xx, 1–6

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/rmed

The effect of corticosteroids on quality of life in a sarcoidosis clinic: The results of a propensity analysis

Marc A. Judson [a,*], Haroon Chaudhry [a], Amanda Louis [b], Kevin Lee [b], Recai Yucel [c]

[a] Department of Medicine, Division of Pulmonary and Critical Care Medicine, Albany Medical College, Albany, NY, USA
[b] Department of Medicine, Albany Medical College, Albany, NY, USA
[c] Department of Epidemiology and Biostatistics, School of Public Health, State University of New York at Albany, Rensselaer, NY 12144, USA

Received 17 November 2014; accepted 29 January 2015

KEYWORDS
Sarcoidosis;
Quality of life;
Corticosteroids;
Patient reported outcomes

Summary
Background: Both sarcoidosis and its treatment may worsen health related quality of life (HRQoL). We performed a propensity analysis of sarcoidosis-specific HRQoL patient reported outcome measures (PRO) to disentangle the effects of sarcoidosis and corticosteroid therapy on HRQoL in sarcoidosis outpatients.
Methods: Consecutive outpatient sarcoidosis patients were administered modules from two sarcoidosis-specific HRQoL PROs: the Sarcoidosis Health Questionnaire (SHQ) and the Sarcoidosis Assessment Tool (SAT). Patients were divided into those that received $\leq$500 mg of prednisone (PRED-LOW) versus >500 mg of prednisone (PRED-HIGH) over the previous year. SAT and SHQ scores were initially compared in the two corticosteroid groups. Then a multivariate analysis was performed using a propensity score analysis adjusted for race, age, gender and the severity of illness.
Results: In the unadjusted analysis, the PRED-HIGH group demonstrated the following worse HRQoL scores compared to the LOW-PRED group: SHQ Daily ($p = 0.02$), SAT satisfaction ($p = 0.03$), SAT daily activities ($p = 0.03$). In the propensity analysis, the following domains demonstrated worse HRQoL in the PRED-HIGH group than the PRED-LOW group: SAT fatigue ($p < 0.0001$), SAT daily activities ($p = 0.03$), SAT satisfaction ($p = 0.03$). All these differences exceeded the established minimum important difference for these SAT domains. The SHQ

* Corresponding author. Division of Pulmonary and Critical Care Medicine, Department of Medicine, MC-91, Albany Medical College, 47 New Scotland Avenue, Albany, New York 12208, USA.
E-mail address: judsonm@mail.amc.edu (M.A. Judson).

http://dx.doi.org/10.1016/j.rmed.2015.01.019

Physical score appeared to demonstrate a borderline improved HRQoL in the PRED-HIGH versus the PRED-LOW group ($p = 0.05$).). In a post-hoc exploratory analysis, the presence of cardiac sarcoidosis may have explained the quality of life differences between the two corticosteroid groups.

Conclusions: Our cohort of sarcoidosis clinic patients who received $\leq$500 mg of prednisone in the previous year had an improved HRQoL compared to patients receiving $>$500 mg on the basis of two sarcoidosis-specific PROs after adjusting for severity of illness. These data support the need to measure HRQoL in sarcoidosis trials, and suggest that the search should continue for effective alternative medications to corticosteroids.

Introduction

Sarcoidosis is a disease with varying presentations, severity, and prognosis [1,2]. In a sizable percentage of sarcoidosis patients, the disease may cause minimal to no symptoms and no significant organ involvement [3,4]. Because the standard treatment of sarcoidosis is corticosteroids [5], the toxicities of these medications may more than offset their benefit in sarcoidosis patients with negligible to mild disease [5]. Therefore, the decision to use corticosteroids for the treatment of sarcoidosis must weigh the benefits of therapy against the potential complications of such treatment.

A previous study of sarcoidosis patients, those who were prescribed corticosteroids were found to have lower health related quality of life (HRQoL) scores than those not receiving corticosteroids [6]. However, it could be argued that patients receiving corticosteroids had more severe sarcoidosis, and that the cause of the poorer HRQoL may have been because of the disease itself rather than the use of corticosteroids. We conducted a trial examining patient reported outcome (PRO) HRQoL measures in patients who were receiving variable corticosteroid dosages. We attempted to adjust for the severity of sarcoidosis in this cohort by using propensity scores in an attempt to disentangle the effects of corticosteroids and sarcoidosis severity upon HRQoL.

Methods

This study was approved by the Institutional Review Board of Albany Medical College. We enrolled consecutive patients into this trial who met the following criteria: a) met diagnostic criteria for sarcoidosis [7]; b) were willing to sign the study consent form; c) were able to converse and read English; d) were greater than 18 years old; and e) had been diagnosed with sarcoidosis at least 1 year prior to enrollment. Subjects could be enrolled if they had pulmonary and/or extrapulmonary sarcoidosis. Subjects were excluded if they were receiving corticosteroids for a medical condition other than sarcoidosis or, if in the opinion of the investigator, they had an alternative medical condition that was severely impairing their HRQoL.

After signing an informed consent form, a study investigator questioned each subject concerning their corticosteroid use over the previous year. The investigator accessed to the subject's medical record to assist in this determination. Through this process, an estimate of the total dose of prednisone equivalent taken by the patient over the last year was made. All subjects were then asked to complete the following PROs: a) the Sarcoidosis Health Questionnaire (SHQ) [8], b) the following Sarcoidosis Assessment Tool (SAT) modules [9,10]: daily activities, satisfaction, pain, fatigue, lung (if the subject had lung involvement by National Institutes of Health A Case Control Etiologic Study of Sarcoidosis - ACCESS criteria [11]), skin (if the subject had skin involvement by ACCESS criteria [11]). All subjects also had the following clinical data recorded: age, sex, race, height, weight, systolic and diastolic blood pressure, date of onset of symptoms of sarcoidosis as estimated by a study investigator (MAJ), date of diagnosis of sarcoidosis as estimated by a study investigator (MAJ), the number of organs involved and specific organs involved by ACCESS criteria [11], the presence of absence of lupus pernio, the date and type of the most recent chest imaging study prior to study entry as well as the Scadding stage [12] on that imaging study, the date of the most recent spirometry testing prior to study entry as well as the forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1) measured on that spirometry study, an inventory of all non-corticosteroid anti-sarcoidosis medications used in the previous 1 year.

Statistical analysis

The patients were divided into 2 groups in terms of corticosteroid use over the previous; those who received $\leq$500 mg of prednisone equivalent over the previous year (PRED-LOW group) and those who received $>$500 mg equivalent over the previous year (PRED-HIGH group). We first conducted a bivariate analyses to compare study sample characteristics between the PRED-LOW and PRED-HIGH groups. Next we compared SAT and SHQ scores (unadjusted) by the two groups. We then conducted multivariate analyses, that aimed to adjust for the differential distributions in the background covariates. As the data under consideration arose from an observational study design and to achieve a pseudo-randomization, propensity score (PS) analysis was used to reduce potential bias and address confounding when comparing PRED-HIGH versus PRED-LOW groups. PS analysis uses matched cases where the matched cases have similar background

Please cite this article in press as: Judson MA, et al., The effect of corticosteroids on quality of life in a sarcoidosis clinic: The results of a propensity analysis, Respiratory Medicine (2015), http://dx.doi.org/10.1016/j.rmed.2015.01.019