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Perspectives of Glucocorticoid Use in Patients with Rheumatoid Arthritis

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Objective. Prednisolone is an effective oral glucocorticoid for managing symptoms of rheumatoid arthritis (RA) but has predictable and common adverse effects. We explored patient perspectives of prednisolone use in RA.

Methods. Patients with RA registered with the Australian Rheumatology Association Database (ARAD) who had completed an ARAD questionnaire in the preceding 12 months were invited to participate in an online survey. Responses were linked to already collected respondent demographics, medication use, and patient-reported outcome measures. The Beliefs about Medicine Questionnaire (BMQ) measured patient beliefs on medication necessity and concerns. Free-text responses outlining reasons for stopping or declining prednisolone underwent thematic analysis using NVivo 12.

Results. The survey response rate was 79.6% (804/1010), including 251 (31.2%) reporting current prednisolone use and 432 (53.7%) reporting previous use. Compared with previous users, current users were older ($P = 0.0002$) and had worse self-reported pain, disease activity, health-related quality of life, and function (all $P < 0.001$). Current users had higher BMQ scores for prednisolone-specific necessity (3.6 versus 1.7; $P < 0.001$) and concerns (2.7 versus 2.3; $P < 0.001$). In previous prednisolone users (n = 432), the most frequent themes identified in free-text responses for cessation were adequate disease control (30.3%), adverse effects (25.2%), and predetermined short courses (21.3%). Of respondents citing adverse effects for cessation (n = 131), weight gain (27.5%), osteoporosis (14.7%), and neuropsychiatric issues (13.8%) were most frequent.

Conclusions. In our cohort, patients with RA taking prednisolone believed it was necessary yet remained concerned about its use. Adequate disease control and adverse effects were important considerations for patients using prednisolone.

INTRODUCTION

Rheumatoid arthritis (RA) is a chronic inflammatory joint disease associated with significant morbidity and disability. Prednisolone is an effective and fast-acting glucocorticoid agent with both anti-inflammatory and disease-modifying properties in RA (1,2). It is the most common oral glucocorticoid prescribed in Australia, with equivalent potency to oral prednisone. Prednisolone has played an important role in the management of RA since the 1950s and is still a commonly prescribed treatment (3), with 50% of patients with incident RA receiving glucocorticoids in the primary care setting (3) and persistent use reported in up to one-third of patients with RA (4,5). It is, however, associated with many adverse effects, especially in the settings of high-dose therapy and long-term use (6). For this reason, current guidelines recommend limiting

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prednisolone use in RA to the initial treatment after diagnosis, during flares of disease activity, and as a bridging therapy while waiting for disease-modifying antirheumatic drugs (DMARDs) to take effect (7,8).

Despite a long history of use in this condition, information about the patient experience of prednisolone therapy in RA is lacking. There has been increasing interest in patient perspectives of glucocorticoid use (9–14), with the recognition that patient perspectives and beliefs are important to clinical management and correlate with treatment adherence and satisfaction (15,16). However, the current available literature focuses largely on adverse effects, with less attention on other aspects of the patient perspective.

Our study aimed to explore patient perspectives about prednisolone use for patients with RA registered in a national inflammatory arthritis database.

METHODS

The Australian Rheumatology Association Database (ARAD) is a prospective registry of patients with inflammatory arthritis, as detailed in previous publications (17–19). Patient-reported outcome measures are collected on a 6- to 12-month basis; at the time of this study, 69% of ARAD participants were opting to complete their usual questionnaires online. Patients with RA registered with ARAD who had completed an online ARAD questionnaire in the previous 12 months were invited to participate in an online survey using Survey Monkey (20). A link to the survey was sent by email to 1010 participants, with a reminder sent 2 weeks later to those who had not yet responded. The survey link was closed 4 weeks after the initial email was sent.

Data collected from annual ARAD questionnaires, including demographic information, medication use, and Assessment of Quality of Life and Health Assessment Questionnaire (HAQ) scores, were extracted from the ARAD database.

The survey collected information on prednisolone use as well as patient attitudes and beliefs about medicines, including prednisolone. Participants were asked to select one of the following four options in response to the question "Are you on prednisolone?": *1*) "I was not offered prednisolone by my doctor," *2*) "I was offered prednisolone but I declined," *3*) "I used to take prednisolone but it was stopped," and *4*) "I am currently taking prednisolone." Self-reported prevalence of current or prior prednisolone use was calculated on the basis of these responses. Respondents reporting prednisolone refusal or cessation were also asked to provide free-text responses outlining their reasons for stopping or declining this medication. Free-text responses were not collected from those not offered prednisolone or with current use.

Respondents with current or prior prednisolone use also completed the Beliefs about Medicines Questionnaire (BMQ) (21). The BMQ consists of two parts, each comprised of two subsections; one assesses beliefs about the general overuse (eg, "doctors use too many medications") and harms (eg, "medicines do more harm than good") of medicines, and the second assesses specific beliefs about the necessity of prednisolone for controlling disease (eg, "without my prednisolone I would be very ill") and concerns about its use (eg, "my prednisolone disrupts my life"). Respondents indicated their level of agreement with each item in the questionnaire on a five-point Likert scale (1 = strongly disagree to 5 = strongly agree). Average scores for each of the four BMQ subsections were calculated separately to reflect the overall beliefs of two different groups (those with current prednisolone use and those with prior use) (16). The BMQ was developed and validated using responses from patients with nonrheumatic chronic disease (21). Criterion and discriminant validity were established in these patient groups, and its use has been broadened to other settings, including patients with RA (15,22).

Statistical analysis was performed using Stata version 15.1 (23). Differences in demographics, medication use, and self-reported disease scores between all prednisolone use groups, as well as between current and prior prednisolone users, were examined using the Pearson χ^2 test and the Kruskal-Wallis rank test. Average BMQ scores for current and prior prednisolone users were compared using t-tests.

Free-text responses outlining reasons for stopping or declining prednisolone were analyzed to identify common themes for prednisolone refusal and cessation. Thematic analysis (24), taking a semantic approach, was conducted by two researchers (GV and JT) until consensus about the themes was achieved. Responses were then coded to these themes using NVivo 12, and the proportion of respondents identifying with each theme was quantified (25). As adverse effects were a predominant theme within reasons for stopping prednisolone, free-text responses referencing adverse effects were additionally analyzed to identify subthemes, and a second round of coding was performed to further explore this area. Word clouds were produced using NVivo 12 to support the generation of themes and subthemes. This analysis method included the application of a stop list of common words to be omitted, removal of spelling errors, and data processing to minimize duplication of words or phrases with equivalent meaning (Supplementary Figure 1). This process was applied iteratively by one researcher (GV) and checked by the second (JT) after the themes were agreed as above.

Ethics approval for ARAD has been obtained from Cabrini Institute (12-23-04-01) and Central Adelaide Local Health Network (HREC/17/TQEH/139). This ARAD substudy was approved by the ARAD Steering Committee before commencing the study.

RESULTS

The survey response rate was 79.6%, with 804/1010 responses received. Of the 683 respondents reporting prednisolone ever-use, 659 (96.5%) completed the BMQ.

Respondents were mostly female (75.1%), with a median age of 61 years and a median disease duration of 17 years.

Table 1. Demographics of respondents by category of prednisolone use

Variable	I Was Not Offered Prednisolone	I Was Offered Prednisolone but Declined	I Used to Take Prednisolone but It Was Stopped	I Am Currently Taking Prednisolone	Total	*P* Value (Joint)	*P* Value (Current Versus Previous)
N (%)	103 (12.8)	18 (2.2)	432 (53.7)	251 (31.2)	804		
Sex, n (%)						0.014	0.23
Female	66 (64.1)	13 (72.2)	341 (78.9)	184 (73.3)	604 (75.1)		
Age, mean (SD), yr	61 (11)	57 (10)	58 (11)	61 (11)	59 (12)	0.003	0.001
Years since Dx, mean (SD)	17 (10)	16 (11)	17 (10)	22 (12)	18 (11)	<0.001	< 0.001
Education, n (%)						0.63	0.14
Primary	1 (1.0)	0 (0)	1 (0.2)	1 (0.4)	3 (0.4)		
Some Secondary	14 (13.6)	2 (11.1)	57 (13.2)	43 (17.1)	116 (14.4)		
Completed Secondary	27 (26.2)	4 (22.2)	103 (23.8)	68 (27.1)	202 (25.1)		
Postsecondary	61 (59.2)	12 (66.7)	271 (62.7)	139 (55.4)	483 (60.1)		
HAQ, mean (SD)	0.5 (0.6)	0.9 (0.6)	0.7 (0.7)	1.1 (0.8)	0.8 (0.7)	<0.001	<0.001
Pain in last week, mean (SD)	34 (26)	46 (24)	35 (26)	47 (25)	39 (26)	<0.001	<0.001
Arthritis condition, mean (SD)	28 (24)	39 (21)	31 (26)	43 (24)	34 (26)	<0.001	<0.001
AqoL Score, mean (SD)	0.66 (0.21)	0.55 (0.23)	0.64 (0.23)	0.51 (0.24)	0.60 (0.24)	<0.001	<0.001
Methotrexate use (current)	65 (63.1)	11 (61.1)	272 (63.0)	157 (62.5)	505 (62.8)	0.11	0.90
Biological DMARD use (current)	61 (59.2)	12 (66.7)	290 (67.1)	157 (62.5)	520 (64.7)	0.39	0.23
Other DMARD use (current)	39 (37.9)	8 (44.4)	144 (33.3)	104 (41.4)	295 (36.7)	0.17	0.034
NSAID use (current)	40 (38.8)	11 (61.1)	174 (40.3)	105 (41.8)	330 (41.0)	0.34	0.69

AQol, Australian Quality of Life Questionnaire; DMARD, disease-modifying antirheumatic drug; Dx, diagnosis; HAQ, Health Assessment Questionnaire; NSAID, nonsteroid anti-inflammatory drug.

The majority (60%) had post secondary education. Compared with those who did not respond, survey respondents were older (median age 61 years versus 58 years; $P = 0.0002$) and more likely to be taking biologic agents (65% versus 53%; $P = 0.002$). No other significant differences in demographics, disease activity, or medication use were identified between responders and non-responders (data not shown).

Of the 804 respondents, 251 (31.2%) reported current prednisolone use, and 432 (53.7%) reported previous use. The remaining 121 (15.0%) reported that they had never taken prednisolone, with 103/121 (85.1%) reporting that they had not been offered prednisolone and 18/121 (14.8%) reporting that they had refused prednisolone when offered.

Table 1 compares respondents according to category of prednisolone use. There was no difference in sex or education level between current and previous prednisolone users; however, current users were older and had a longer disease duration. Current users also reported higher levels of pain, poorer disease control, greater disability, and poorer health-related quality of life. There were no significant differences between current and previous prednisolone users with respect to methotrexate, biologic agents, or nonsteroidal anti-inflammatory drug use, but current users were more likely to be taking other DMARDs compared with those with previous use (41.4% versus 33.3%; $P = 0.034$).

Prednisolone-specific and general BMQ scores for 659/683 (96.5%) respondents with current or prior prednisolone use are shown in Table 2. Current users had a significantly higher prednisolone-specific necessity score (3.6 versus 1.7; $P < 0.001$) and marginally higher, but statistically significant, prednisolone-specific concerns score (2.7 versus 2.3; $P < 0.001$) when compared with previous users. There was no significant difference in general BMQ scores between these two groups for medication overuse or harms.

Of the 18 respondents who declined prednisolone, two-thirds (n = 12) expressed concerns about potential adverse effects. Examples include "I had read negative comments about prednisolone" and ''did not want to be on steroids, am already overweight."

For self-reported previous prednisolone users (N = 432), the main reasons for stopping included adequate disease control (n = 131; 30.3%), adverse effects (n = 109; 25.2%), and prescribed short courses (n = 92; 21.3%) (Figure 1B). Prednisolone cessation was attributed to the commencement of biologic agents in 78 (18.1%) respondents. Example quotes from free-text responses by theme are displayed in Figure 1A. These themes were reflected in the word cloud in Figure 1C, as follows: adequate disease control ("need," "required," "control," and "better"), adverse effects ("side effects," "weight gain," and "weight"), predetermined short-term use ("short course," "flare," and "time"), medical advice ("doctor," "prescribed," and "weaned"), and biological DMARD treatment.

Pregnancy and breastfeeding were cited by 11 respondents, with most (7/11) indicating that it was used in the pregnancy and breastfeeding periods, whereas the remainder indicated that they stopped in these periods.

Overlapping themes for stopping prednisolone were identified in some responses (Supplementary Figure 2). Of the 131 responses describing adequate disease control, the commencement of a biologic agent was also noted in 35 (26.7%) respondents, and a predetermined short course was specified by 14 (10.6%) respondents. Of the participants citing a predetermined short course for prednisolone cessation, 14/92 (15.2%) also reported adverse effects as a reason for prednisolone cessation.

The theme of adverse effects was commonly expressed by previous users (109/432; 25.2%) and by those who had declined prednisolone (12/18; 66.7%). The most common adverse effects reported by previous users were weight gain (n = 30; 27.5%), osteoporosis (n = 16; 14.7%), and neuropsychiatric complaints (n = 15; 13.8%) (Figure 2B). Example quotes from free-text responses by subtheme are displayed in Figure 2A. These subthemes are represented in the word cloud in Figure 2C, as follows: weight gain ("weight gain," "weight," "gained," and "appetite"), osteoporosis ("bone," "bones," "density," and "osteoporosis"), and neuropsychiatric effects ("high," "anxiety," and "sleep"). Other adverse effects described included Cushingoid features (n = 10; 9.2%), impaired glucose tolerance (n = 9; 8.3%), malaise (n = 8; 7.3%), and hypertension (n = 5; 4.6%). The specific adverse effects experienced were not specified for 24/109 (22.0%) responses.

DISCUSSION

This study examined patient perspectives on prednisolone use in a cohort of patients with RA participating in a national inflammatory arthritis database. Although adequate disease control was the most commonly cited reason for stopping prednisolone, adverse effects were also a key consideration for both

Table 2. Beliefs about Medicines Questionnaire in those with previous and current prednisolone use

BMQ	Prednisolone Use		Difference	*P* Value
	Previous (n = 417)	Current (n = 242)		
Prednisolone-specific concerns	2.3 (2.2 to 2.4)	2.7 (2.6 to 2.8)	0.4 (0.2 to 0.5)	<0.001
Prednisolone-specific necessity	1.7 (1.6 to 1.7)	3.6 (3.5 to 3.7)	2.0 (1.8 to2.1)	<0.001
General overuse	2.6 (2.6 to 2.7)	2.6 (2.5 to 2.7)	0.0 (−0.2 to 0.1)	0.85
General harms	2.1 (2.1 to 2.2)	2.2 (2.1 to 2.3)	0.1 (0.0 to 0.2)	0.31

Data are given as mean (95% confidence interval); scores use a five-point Likert scale (1 = strongly disagree to 5 = strongly agree).

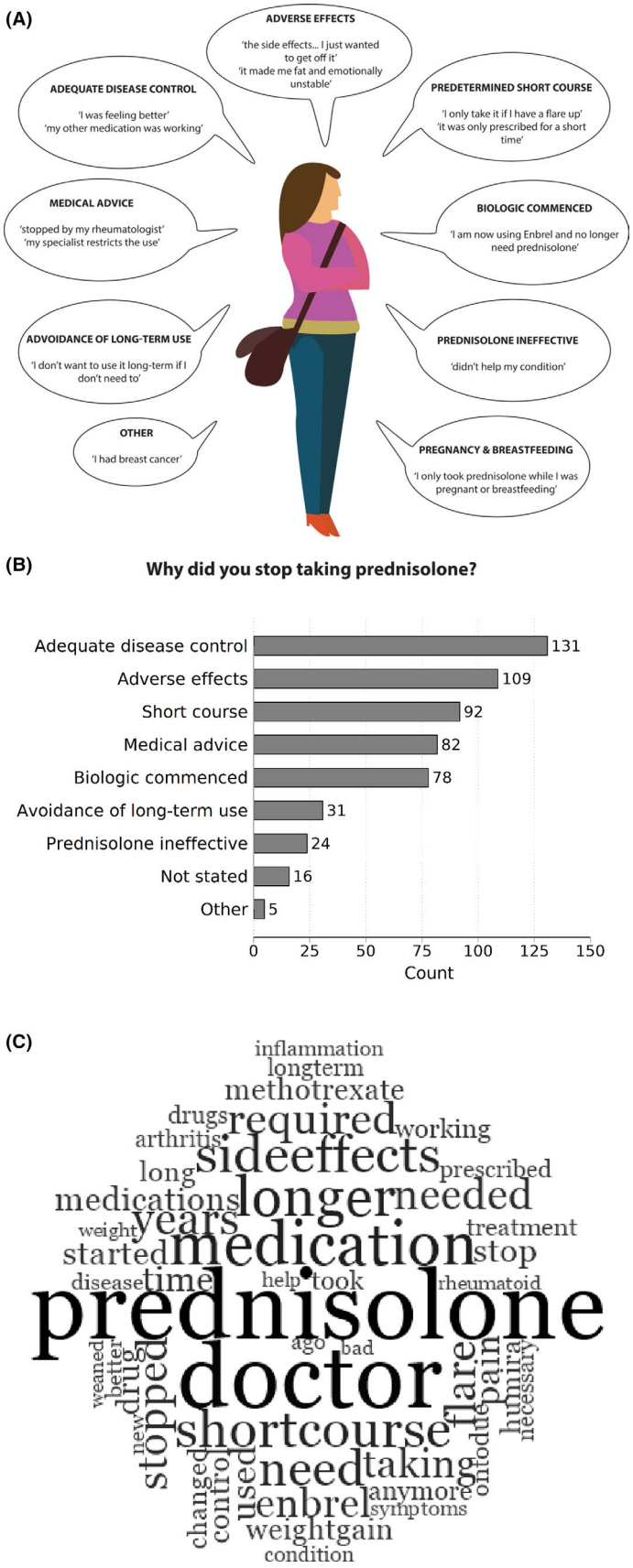

Figure 1. Reasons for stopping prednisolone: example quotes from free-text responses by theme (*A*), bar chart representing the quantity of respondents identifying with each theme (*B*), and word cloud generated from processed free-text responses (*C*).

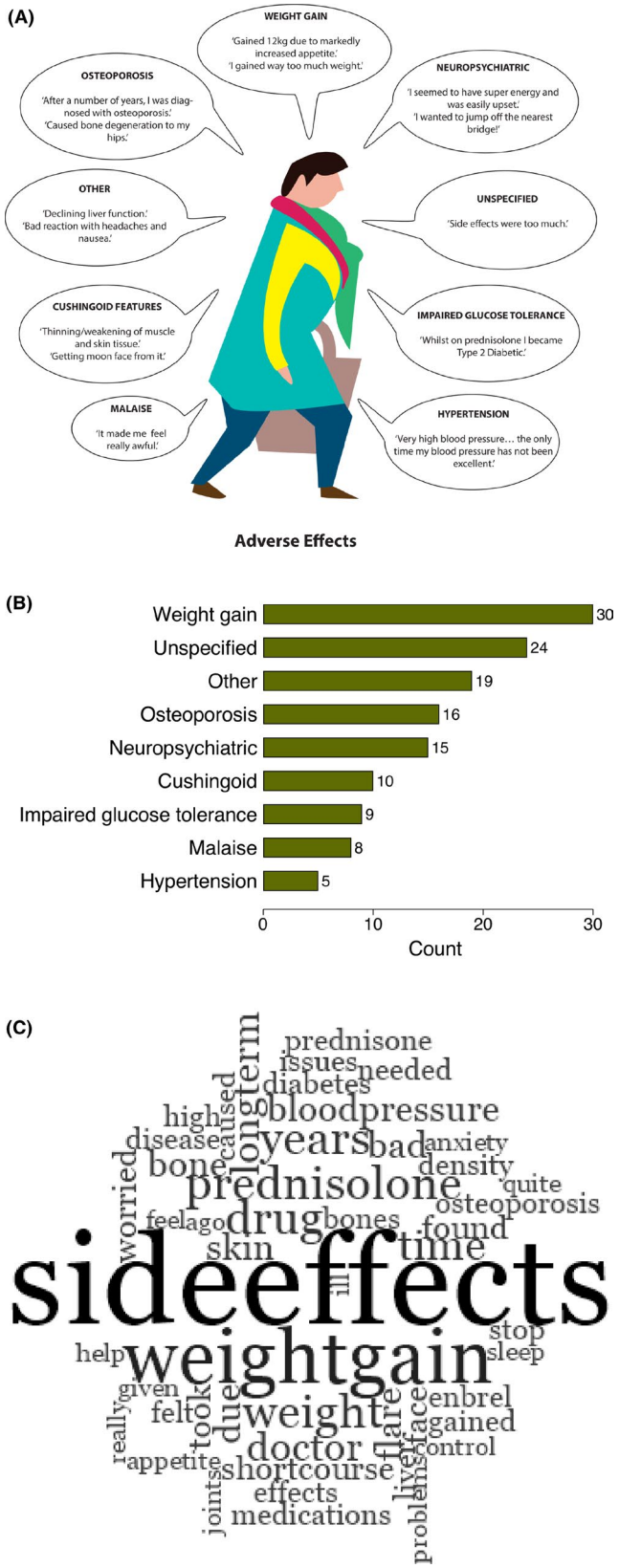

Figure 2. Adverse effects of previous prednisolone use: example quotes from free-text responses by subtheme (*A*), bar chart representing the quantity of respondents identifying with each subtheme (*B*), and word cloud generated from processed free-text responses.

stopping and declining prednisolone. Among those with previous prednisolone use, weight gain, osteoporosis, and neuropsychiatric issues were the most commonly cited adverse effects. Prescribing practices were also an influencing factor, with prednisolone cessation commonly attributed to adequate disease control, prescribed short courses, and commencement of other agents.

The prevalence of prednisolone ever-use in our study was high, with 85% reporting current or prior use. In a multinational cross-sectional study, substantial variation was observed in lifetime ever-use of glucocorticoids (26-88%) (26). Despite this, the prevalence of current prednisolone use in this cohort was slightly lower than that in previous studies (5,27). The use of oral glucocorticoids in RA has decreased over time, with patients less likely to commence prednisolone and more likely to cease it (27,28). Given that our cohort had a median disease duration of 17 years, this may partly account for the higher prevalence of prednisolone ever-use in this study.

Current users had higher levels of self-reported pain, disease activity, functional status, and health-related quality of life when compared with previous users. This is consistent with a previous study evaluating a broader group of 3699 patients from the same national inflammatory arthritis registry, which found that higher HAQ and arthritis activity scores in RA were associated with increased glucocorticoid use (27). Another study also found that patients with RA willing to accept glucocorticoid treatment had poorer disease control and function than those who were not (10). As described in other populations using glucocorticoids (29–32), it is possible that prednisolone may be contributing to disability in this group. However, given that the most common reason for prednisolone cessation in this study was adequate disease control, those requiring prednisolone may also have disease activity that is inherently more difficult to control.

Current prednisolone users were more likely to report that prednisolone was necessary to manage their condition than those with previous use. This may be related to the poorer self-reported disease control in those with current use, as previous studies have described an association between increasing disability and stronger beliefs on medication necessity in patients with RA (16). Further research is required to explore the role of patient beliefs about medication necessity on medication preferences and persistence with the medication. Interestingly, despite reporting greater prednisolone necessity, current prednisolone users remained concerned about its use.

Morrison et al, who also evaluated attitudes of patients with RA about oral glucocorticoids, reported that 46/90 (51%) patients refusing to participate in a trial did so because of concerns about glucocorticoid use (10). Moreover, the study also found that patients were able to list several adverse effects associated with glucocorticoids despite being largely unaware of their role or efficacy in RA management (10). In the 18 respondents to this survey who had declined prednisolone, concerns about potential

adverse effects were the most-reported reason for declining prednisolone (66.7%).

Of the 109 patients who described ceasing prednisolone because of adverse effects, the most frequently identified issues included weight gain, osteoporosis, and neuropsychiatric complaints. To a lesser extent, patients also expressed concern about metabolic effects. This is consistent with the findings of previous studies (9–12,33–35), which have demonstrated that patients place particular importance on adverse effects with greater psychosocial impacts (9,12,35). Clinicians more commonly focus concern on medically serious issues, such as hypertension and impaired glucose tolerance (11,13,34), which were less frequently cited in this cohort. Surprisingly, skin fragility was also less commonly reported compared with other studies. As the analyzed free-text responses asked respondents to provide reasons for stopping prednisolone treatment, dermatological issues may have been experienced without being a primary reason for prednisolone cessation. Similarly, adverse effects commonly identified by clinicians, such as hypertension, are often treatable and may also have occurred without resulting in cessation. The occurrence of adverse effects as a key consideration for both stopping and declining prednisolone highlights the importance of certain adverse effects as factors for patients in treatment decisions around prednisolone when balancing against any positive effects. The social and emotional impacts of treatment have a significant effect on quality of life and adherence (15,16), which may be underestimated by clinicians and thus are important to address. Moreover, patients may not be aware of the seriousness of other adverse effects, and education on these issues may be required. Further research is needed to explore differences in patient and clinician views on prednisolone use in more detail.

There are several limitations to our study, including the inherent limitations of a survey-based approach. The cross-sectional nature of our study prevents us from commenting on causality. Given that our population consisted mostly of older, more highly educated individuals enrolled in a registry and participating regularly in self-reported surveys, our cohort may not accurately reflect the wider RA population. As we were evaluating lifetime use of prednisolone, which may not necessarily have been recent, there is also the potential for recall bias. The wording of questions limited our study to evaluating prednisolone use specifically, and, although prednisolone is the most commonly prescribed glucocorticoid for RA in Australia, other forms of glucocorticoids were not evaluated. Moreover, we did not collect information about patterns of use, dosing, or duration of prednisolone therapy. As free-text data aimed to examine reasons for declining and ceasing prednisolone, free-text data were not collected from patients not offered prednisolone or with current use. Strengths of the study included the excellent response rate, resulting in a large sample of 804 participants. Although most (85%) patients enrolled in ARAD have been prescribed a biologic agent for treatment, previous data have indicated that these patients are nationally representative on the basis of residential postcode, demographic, and clinical characteristics, supporting the generalizability of our findings (19). Furthermore, the current literature evaluating patient perceptions of glucocorticoid use focuses mostly on adverse effects, whereas we were able to expand current knowledge by investigating other aspects of patient experiences and exploring considerations important to patients in decision-making about prednisolone use and discontinuation as well as beliefs about medications.

In conclusion, patients with RA taking prednisolone strongly believed it was a necessary treatment yet remained concerned about its use. The results of this study have highlighted that although cessation occurs with adequate disease control, adverse effects (namely, weight gain, osteoporosis, and neuropsychiatric effects) were a particularly important reason for stopping prednisolone in our cohort of patients with RA. Clinicians should remain mindful of these common reasons for prednisolone cessation in shared decision-making on treatment with patients. The small number of respondents who refused prednisolone without prior experience frequently cited concern about adverse effects, and further research to understand reasons for these beliefs should be explored.

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AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published. Professor Catherine Hill had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design Lester, Leonardo, Hill.
Acquisition of data Lester, Barrett, Rowett, Buchbinder, Hill.
Analysis and interpretation of data Venter, Tieu, Black, Whittle, Hoon, Hill.

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