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Impact of Cyclosporin Treatment on Health-Related Quality of Life of Patients with Alopecia Areata

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TITLE PAGE

TITLE: Impact of Cyclosporin Treatment on Health-Related Quality of Life of Patients with Alopecia Areata

Running Head: Cyclosporin and Quality of Life in Alopecia Areata

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MAIN TEXT

TITLE: Impact of Cyclosporin Treatment on Health-Related Quality of Life of Patients with Alopecia Areata

ABSTRACT:

Introduction: Alopecia areata (AA) is a disfiguring disease with substantial psychological burden. No studies explore the efficacy of pharmacotherapy through health-related quality of life (HRQOL) using both disease-specific and generic quality of life instruments. We present the first study to elicit health utility from patients with AA and to evaluate the efficacy of cyclosporin in relation to HRQOL using both measures.

Methods: Participants with moderate to severe AA from a placebo-controlled randomised trial investigating cyclosporin were administered the generic preference-based HRQOL instrument, Assessment of Quality of Life-8D (AQoL-8D) and the disease-specific HRQOL instrument, Alopecia Areata Symptom Impact Scale (AASIS). HRQOL was measured at each study visit and compared to baseline.

Results: 32 participants were analysed. The mean health utility was 0.748. At 3 months, the cyclosporin group had trends for greater improvement in HRQOL across 6 of 8 AQoL-8D dimensions and 5 of 7 AASIS symptom domains compared to placebo. HRQOL was lower than Australian population norms across 6 of 8 AQoL-8D dimensions.

Conclusion: Patients with AA had a mean health utility of 0.748. Treatment with cyclosporin 4mg/kg/day for 3 months resulted in trends for improvement of HRQOL across multiple dimensions in both disease-specific and generic measures.

Abstract Word Count: 197 (Limit 200)

Keywords: Alopecia Areata, Quality of Life, Cyclosporine, Immunomodulators, AQoL-8D, AASIS, Immunosuppressive Agents, Clinical Trial

Capsule Summary

- The mean health utility for patients with AA was 0.748. Patients with alopecia areata have impaired health-related quality of life across 6 of 8 AQoL-8D dimensions compared to population norms.
- Treatment with oral cyclosporin for moderate to severe AA resulted in trends for improvement in quality of life across multiple dimensions.

Capsule Summary Word Count: 51

INTRODUCTION:

Alopecia areata (AA) is a disfiguring disease with substantial psychological morbidity. Hair is a crucial component of facial identity for both men and women and in an image-oriented society hair loss can be psychologically devastating. More than 50% of patients with AA experience reduced health-related quality of life (HRQOL) (1) and the prevalence of psychiatric disorders in patients with AA is between 66%-74% (2-4). Lifetime prevalence of depression is 39% and prevalence of generalised anxiety disorder is 40%-60% (2-4).

Few treatments are available that produce consistent and extensive hair regrowth. Systemic corticosteroids are often used in disease-progressive cases (5) with good effect, however long-term use is limited by cumulative side-effects. Cyclosporin, azathioprine and methotrexate have been used either as monotherapy or more commonly as second-line steroid-sparing agents. Our placebo-controlled randomized clinical trial investigating cyclosporin efficacy found a response rate in the cyclosporin group to be 31.3% compared to 6.3% in the placebo group (6). It is also important to evaluate whether this increase in hair growth is associated with improvements in quality of life, particularly given its significant psychological morbidity.

In Australia, there is currently no systemic treatment subsidised for AA on the Pharmaceutical Benefits Scheme (PBS). The economic evaluation of subsidised medications involves cost-utility analysis. Utilities represent an assessment of individual's preferences for different health states (7) and are commonly measured through preference-based HRQOL instruments, otherwise known as multi-attribute utility instruments (MAUIs), such as the EQ-5D (8) or Assessment of Quality of Life-8D (AQoL-8D) (9). These instruments enable quantification of health state utility and facilitate calculation of quality-adjusted life-years

(QALYs). QALYs allow comparison of the efficiency of interventions within and across diseases.

While generic MAUIs enable comparison of QALYs across diseases, disease-specific instruments, such as the Alopecia Areata Symptom Impact Scale (AASIS) (10), should provide greater sensitivity and specificity with analysing impacts on quality of life from disease symptoms.

A range of both disease-specific and generic quality of life instruments have been used to investigate HRQOL in patients with AA (11). One systematic review reported a total of 14 different HRQOL measures used in studies, with Dermatology Life Quality Index (DLQI) and SF-36 as the most frequently used measures (11). However, despite this, there are no studies that investigate the impact of pharmacotherapy on quality of life using both disease-specific and generic quality of life measures (12). This step is crucial for decision makers to determine resource allocation; to evaluate the efficacy of a particular pharmacotherapy in comparison to others.

Furthermore, the mean population health state utility of AA is unknown. Health utility scores lies on a 0 to 1 quality-adjusted life years scale, where 0 represents death, and 1 represents full health. There is only one study that has quantified a utility score for AA to be 0.998 (13) using a sample size of 1**,** and which claims this utility is similar to other cosmetic dermatopathology and urticaria. It is clearly evident that more comprehensive estimation of mean utility of AA is required with larger sample sizes. Assessment of utility based from one individual does not equate to a valid and robust result for an entire disease cohort (13, 14).

We conducted the first randomised, placebo-controlled trial investigating the efficacy of oral cyclosporin in patients with moderate to severe AA and employed both the generic MAUI, AQoL-8D, and the disease-specific HRQoL instrument, AASIS.

The objectives for this study were to evaluate the health utility of AA patients in this cohort, to evaluate impairments on dimension scores as measured by the AQoL-8D and AASIS, to compare AQoL-8D utility scores with the Australian norm, to assess changes in AQoL-8D and AASIS scores after systemic cyclosporin treatment and to determine correlations between AA symptoms as measured by AASIS and health state utility as measured by AQoL-8D in a cohort of moderate to severe AA patients.

MATERIALS AND METHODS:

Study Cohort

This cohort comprised participants of a randomised, placebo-controlled trial investigating the efficacy of 4mg/kg/day oral cyclosporin (6). Participants were adults, aged 18 to 65 years of age, with moderate to severe AA. Participants did not take any additional medication that could promote hair regrowth apart from their allocated study medication. All participants were proficient in English. There were no additional inclusion or exclusion criteria from those of the clinical trial for this quality of life assessment (6).

Clinical Trial and Quality of Life Assessment

The clinical trial was a single-centre, double-blind, randomised, placebo-controlled study conducted in Melbourne, Australia. Briefly, participants were allocated in a 1:1 ratio to receive either 4mg/kg/day oral cyclosporin or matching placebo in the trial. There was a total of 6 visits over a maximum of 21 weeks for each trial participant. Quality of life assessments

were completed monthly at each check-up visit to the clinic. Participants self-completed 2 questionnaires, the AASIS and the AQoL-8D, at each study visit from randomisation (Visit 2) to end-of-study (Visit 6). Any queries were clarified by the study investigator without promoting an answer.

Data Analysis

Health state utility scores were calculated using an Australian-specific tariff for the AQoL-8D (15) and each dimension was compared with Australian population norms (16). Subgroup analyses for utility scores were calculated and compared using one-tailed Mann Whitney U tests. Global Symptom Impact Score, Global Interference Score and individual symptom scores were calculated from the AASIS.

The Global Symptom Impact Score is an unweighted average of all AA symptom impacts (scalp hair loss, body or eyelash hair loss, tingling/numbness of the scalp, itchy or painful skin, irritated skin, feeling anxious or worried, feeling sad) on a scale of 0 (all symptoms not present) to 1 (all symptoms as bad as you can imagine).

The Global Interference Score is an unweighted average of all domains in which AA interferes with daily functioning (work, enjoyment of life, interaction with others, daily activities, sexual relationships, quality of life) on a scale of 0 (no interference at all) to 1 (complete interference).

The baseline Global Symptom Impact Score and Global Interference Score were correlated to the AQoL-8D utility score to determine correlation between disease symptoms specifically measured with the AASIS and overall mean health utility. A per protocol analysis (only

participants who completed the clinical trial) was conducted to determine changes in quality of life after pharmacotherapy as measured by the AQoL-8D and AASIS. All statistical analyses were conducted using Stata 12 statistical software.

RESULTS:

32 participants who completed the full clinical trial at 3 months (Figure 1) were analysed in this per protocol quality of life assessment (6).

Participant Characteristics

Participant characteristics at baseline are summarised in Table 1. Full demographic and clinical characteristics of all randomised participants for this clinical trial have been previously published (6).

Between cyclosporin and placebo groups respectively, participants had similar percentage scalp hair loss by SALT score at baseline (77.8% versus 81.1%, p=0.56) and a similar percentage of patients from each group had AT/AU (55.5% versus 61.1%, p=0.92).

At baseline, on average participants in the cyclosporin group had slightly worse Global Symptom Impact Scores (0.401 versus 0.380, p=0.76) and Global Interference Scores (0.327 versus 0.314, p=0.88) compared to placebo. There was a marginally worse baseline AQoL-8D utility score in the cyclosporin group compared to placebo (0.739 versus 0.756, p=0.68). Psychological comorbidities, including depression and anxiety, were noted in 2 patients on cyclosporin and none in placebo patients. Adjustment for these baseline differences did not significantly alter the final results.

Correlation between AASIS and AQoL-8D

At baseline, there was a strong negative correlation between Global Symptom Impact Scores and Global Interference Scores of the AASIS with AQoL-8D utility scores (Both Spearman's correlation coefficient = -0.73).

HRQOL as measured by the AQoL-8D

Mean health utilities of participants with AA are presented in Table 2. At baseline, the mean health utility for all patients with AA was 0.748. The mean health utility for patients with AT/AU was 0.733 compared to 0.773 for patients with patchy AA (p=0.39). Female patients had lower mean utility compared to male patients (0.738 versus 0.791 respectively, p=0.07), as did patients aged 18 to 30 years compared to those aged 46 to 65 years (0.678 versus 0.789 respectively, p=0.07).

HRQOL improved over time for both the cyclosporin and placebo groups during the clinical trial (Figure 2). This improvement was greater for the cyclosporin group than the placebo group (0.064 versus 0.050, p=0.763). The HRQOL for the cyclosporin group was consistently below the Australian population norm at baseline, 1 month and 2 months of treatment (Figure 2) and improved above the Australian population norm at 3 months, whereas in the placebo group the HRQOL improved above the Australian population norm after the 1st month of treatment (Figure 2).

At baseline in the cyclosporin group, 6 out of 8 AQoL-8D dimension scores were below the Australian population norm: happiness, mental health, coping, relationships, self-worth and sensation (Figure 3). At 3 months of treatment, only happiness and sensation improved to a score equal to or above the Australian population norm; whereas mental health, coping,

relationships and self-worth dimensions improved at 3 months but at a score still lower than the Australian population norm (Figure 3).

At baseline in the placebo group, 6 out of 8 AQoL-8D dimension scores were also below the Australian population norm: independent living, happiness, mental health, coping, self-worth and sensation (Figure 3). At 3 months of treatment, independent living, happiness, coping and sensation improved to a score equal to or above the Australian population norm (Figure 3).

Trends in improvement in dimension scores at the end of 3 months treatment were greater for the cyclosporin group than placebo group in 6 of 8 dimensions including: independent living, happiness, mental health, relationships, self-worth and sensation.

HRQOL as measured by the AASIS

There were trends for improvement in the Global Symptom Impact score at the end of 3 months in the cyclosporin group, whereas trends for deterioration in the placebo group (Figure 4). Similarly, the Global Interference Score trended towards improvement at the end of 3 months in both the cyclosporin and placebo group (Figure 5). Figure 6 displays each AA symptom as measured by the AASIS and average scores over time for the cyclosporin and placebo group. Overall, the cyclosporin group had greater trends in improvement in AA symptoms compared to placebo, with improvements in 5 of 7 symptom domains: body or eyelash hair loss, itchy or painful skin, irritated skin, feeling anxious or worried and feeling sad. The placebo group, in contrast, only had an improvement in itchy or painful skin at the end of 3 months.

DISCUSSION:

Key findings

This study represents the largest study to evaluate health utility in AA patients as well as the only study to determine impact of systemic treatment on quality of life.

This is the first clinical trial to employ both disease-specific and a generic MAUI to comprehensively evaluate the impact of pharmacotherapy on HRQOL. There was a strong negative correlation between the Global Symptom Impact Score and Global Interference Score of the AASIS with the AQoL-8D utility score at baseline.

In this study, the cyclosporin group had both a greater number of dimensions with improvement and a greater quantity of improvement at the end of 3 months treatment, compared to the placebo group as measured by both the AQoL-8D and AASIS.

Patients with AA had a mean health utility of 0.748 as quantified by the AQoL-8D. Female patients, those aged 18 to 30 years of age and patients with AT/AU had on average lower health utility at baseline.

Trends for improvement were found in 6 of 8 dimensions of the AQoL-8D and 5 of 7 symptom domains on the AASIS in the cyclosporin group. This is compared to improvement in only 2 of 8 dimensions of the AQoL-8D and 1 of 7 symptom domains on the AASIS in the placebo group.

At the end of 3 months, AQoL-8D scores improved more for cyclosporin than placebo, and Global Symptom Impact score improved for cyclosporin but not for placebo, however these results were not statistically significant.

The HRQOL of this moderate to severe cohort of AA patients was also below the Australian population norm for a number of utility dimensions as measured by the AQoL-8D.

Interpretation of findings

These results suggest that treatment with cyclosporin at 4mg/kg/day for 3 months improves quality of life across a range of dimensions compared to placebo. The response rate in the cyclosporin group was 31.3% compared to 6.3% in the placebo group (6), and this response was seen to improve dimensions such as happiness, mental health, relationships and self-worth at the end of 3 months.

Patients with AA had significantly reduced health utility of 0.748 as quantified by the AQoL-8D. This represents a great difference in health utility from what was previously quantified to be 0.998 (13) albeit from a study which only had a sample size of 1. Subgroup analysis revealed that females, younger patients aged 18 to 30 years of age and those with greater disease extent with AT/AU had lower mean health utility, suggesting a greater psychological impact given these risk factors.

While the change in HRQOL scores did not reach statistical significance at 3 months, the trends in improvement suggest that a larger sample size may help significantly detect these differences. There may also be an element of delayed psychological adjustment for increased hair regrowth in our cohort of moderate to severe, long-standing disease. It is known that the

unpredictable nature of AA contributes to the psychological morbidity (17); therefore participants in this 3-month trial may require a greater adjustment period to believe that hair will persist following treatment, rather than shedding again, resulting in a delay in psychological improvement. Nevertheless, consistent trends existed for improvement in the cyclosporin group compared to placebo.

The strong negative correlation between the AASIS and AQoL-8D also suggests that a greater degree of AA disease symptoms (such as scalp hair loss, eyebrow or eyelash loss) is linked with poorer quality of life.

HRQOL in patients with AA was poorer compared to the Australian population norm across a number of utility dimensions, suggesting widespread disease burden.

Relationship with similar literature

Systematic reviews highlight the great impact of AA on HRQOL across a range of dimensions, most significantly role-emotional, mental health and vitality (11, 18). Our use of the AQoL-8D captured a greater range of psychosocial dimensions affected and found HRQOL reduced across 6 of 8 domains. This is the first study to employ the AQoL-8D in a cohort of AA patients, having previously been applied to other chronic diseases such as asthma and rheumatoid arthritis (9). The AASIS has previously been administered to 452 AA participants in a study showing reliable internal consistency and content validity (10). This is also the first study to utilise the AASIS to evaluate the impact on quality of life from pharmacotherapy.

Study strengths and limitations

We utilised both generic preference-based and disease-specific HRQOL instrument that have been validated to capture the impact on quality of life. The importance of using generic preference-based HRQOL instruments has been overlooked in the literature thus far, with almost no studies reporting the mean health utility of AA. In our study, we not only use the generic instrument, AQoL-8D to quantify health utility in AA, representing the largest study cohort to do so to date, but also link the data from the disease-specific instrument with the generic instrument, to show an association between symptoms and the overall health state utility.

We chose the AQoL-8D as an appropriate generic MAUI in this cohort as it more comprehensively evaluates psychosocial dimensions of quality of life, compared to other generic MAUIs such as the EQ-5D. The AASIS was chosen as our disease-specific HRQOL instrument having been shown to have good content validity and internal consistency. Compared to other AA-specific instruments, namely the Alopecia Areata Quality of Life Index (AA-QLI) and Alopecia Areata Quality of Life (AAQ), the AASIS has been validated in the largest AA population to date (11).

Our study is mainly limited by a small cohort size. Larger randomised controlled trials with a sample size calculated on both treatment and quality of life efficacy would be beneficial to detect these changes.

Conclusion

Patients with AA had a mean health utility of 0.748 as quantified by the AQoL-8D. In moderate to severe AA patients, HRQOL was lower than Australian population norms across 6 of 8 dimensions. Greater symptom severity and greater interference with daily functioning were strongly correlated with poorer HRQOL. Treatment with cyclosporin 4mg/kg/day for 3 months resulted in trends for improvement in the quality of life of patients across a range of dimensions compared to placebo on both the AQoL-8D and AASIS.

ACKNOWLEDGEMENTS

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FIGURES LEGENDS

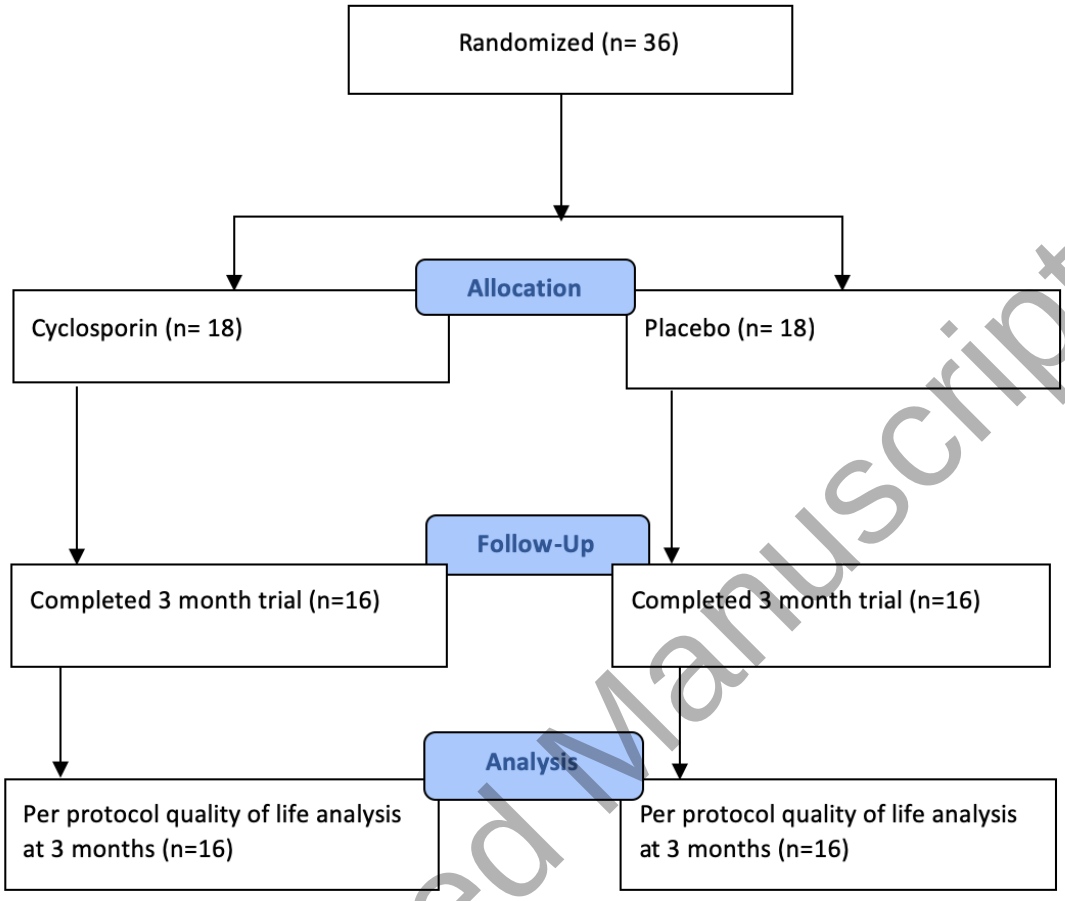

Figure 1. Participants completing clinical trial and analysed.

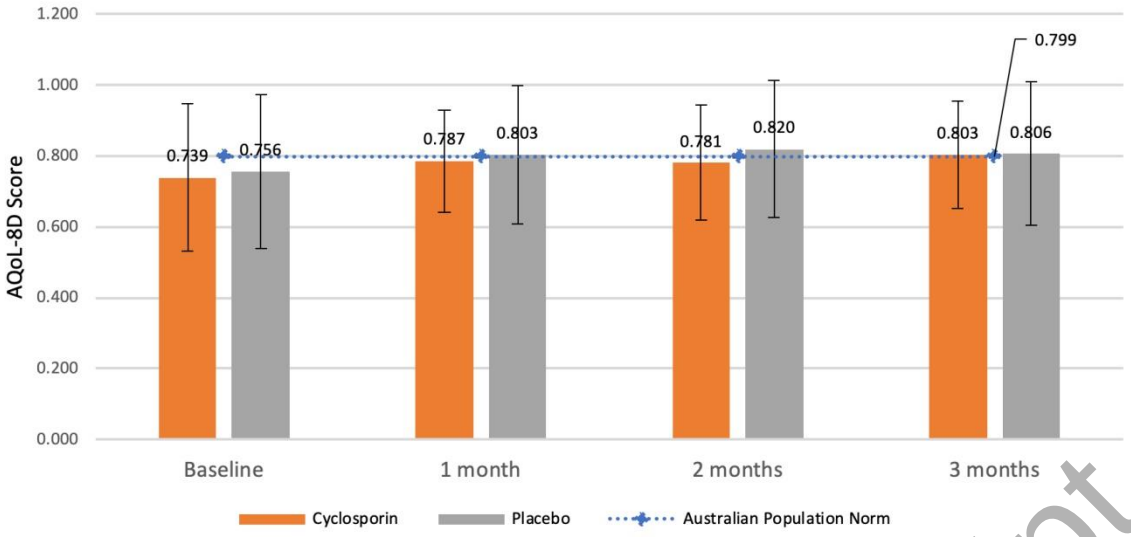

Figure 2. AQoL-8D utility scores over time

The AQoL-8D scale measures QOL on a scale from 0 (death) to 1 (full health). The dotted line represents the Australian population norm.

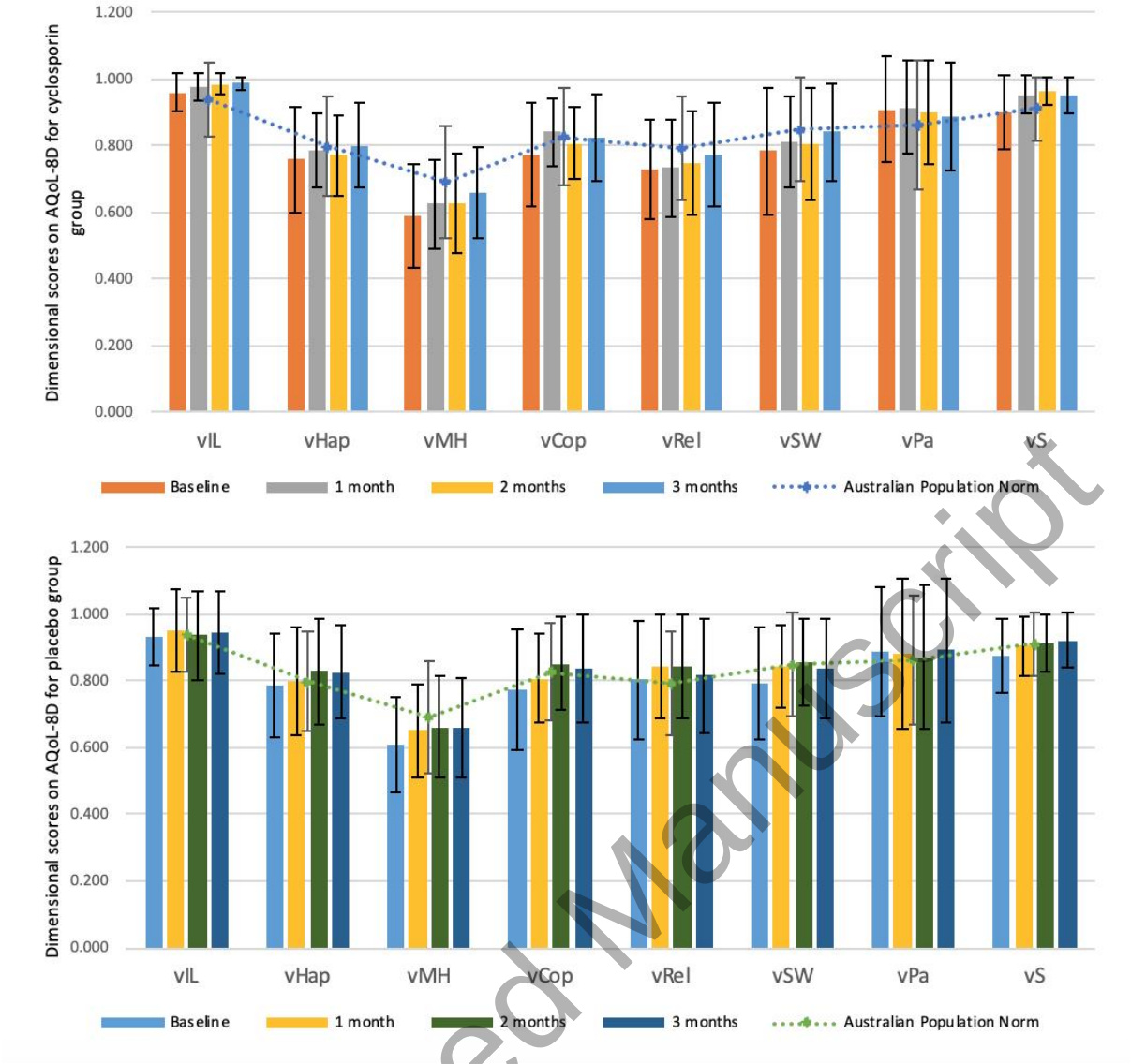

Figure 3. Dimension scores of AQoL-8D in cyclosporin and placebo groups over time compared with Australian population norms

vIL: independent living; vHap: happiness; vMH: mental health; vCop: coping; vRel: relationship; vSW: self-worth; vPa: pain; vS: sensation. The dotted line represents the Australian population norm.

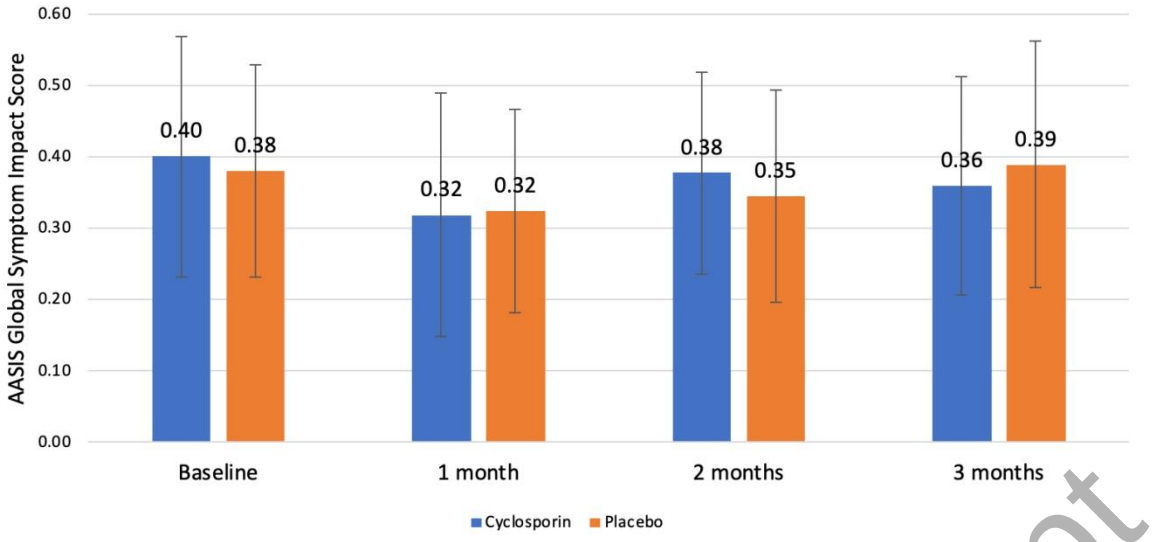

Figure 4. Global Symptom Impact score over time

The Global Symptom Impact Score is an unweighted average of all AA symptom impact on a scale of 0 (all symptoms not present) to 1 (all symptoms as bad as you can imagine). Symptoms included are: scalp hair loss, body or eyelash hair loss, tingling/numbness of the scalp, itchy or painful skin, irritated skin, feeling anxious or worried, feeling sad.

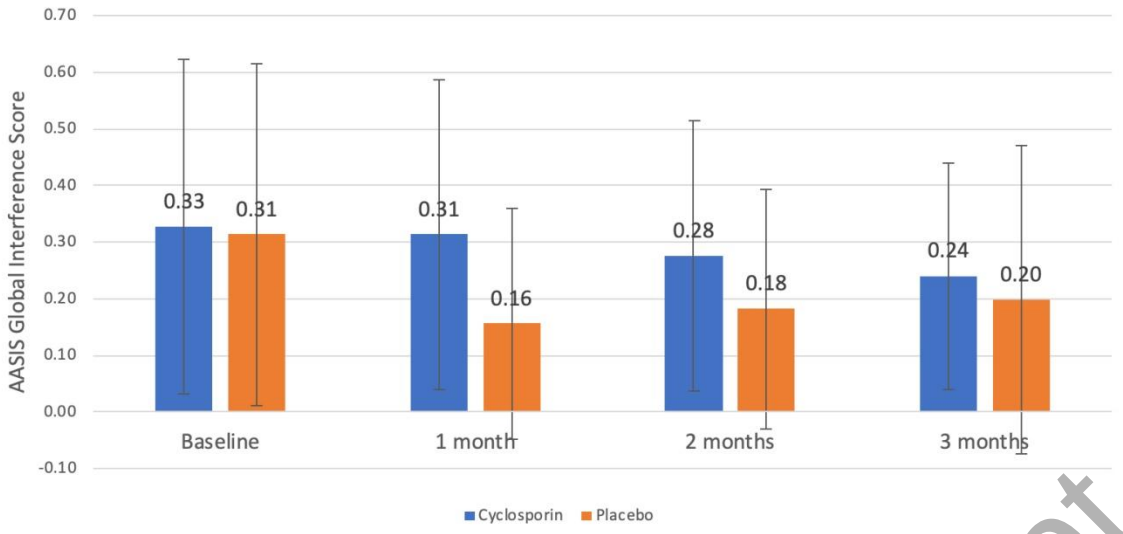

Figure 5. Global Interference Score over time

The Global Interference Score is an unweighted average of all domains in which AA interferes with daily functioning on a scale of 0 (no interference at all) to 1 (complete interference). Domains of interference include: work, enjoyment of life, interaction with others, daily activities, sexual relationships, quality of life.

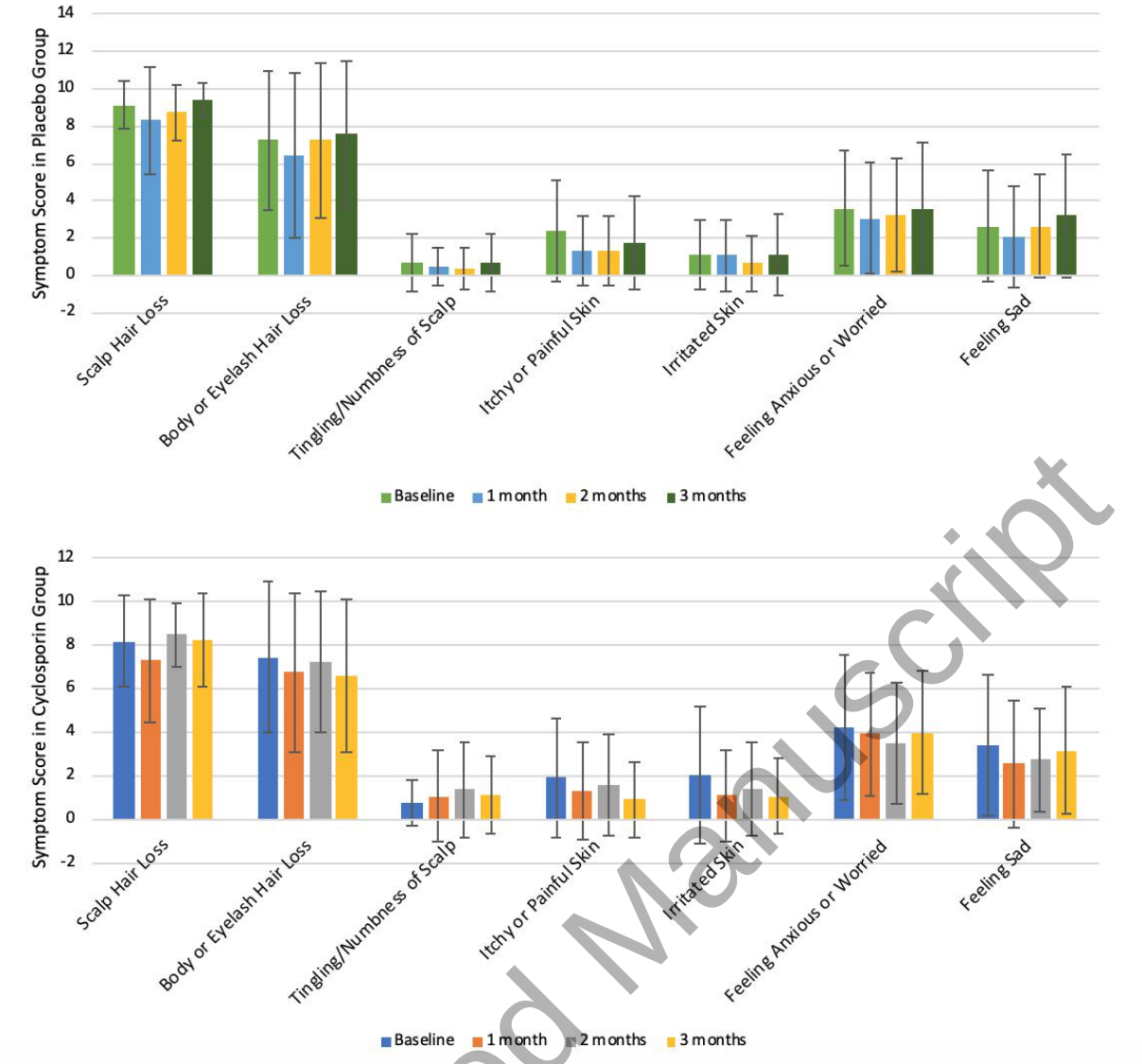

Figure 6. Symptom scores for cyclosporin and placebo groups over time

Each symptom is rated from 0 (not present) to 10 (as bad as you can imagine).

TABLES

Table 1. Baseline participant characteristics

	All (n=36)	Cyclosporin (n=18)	Placebo (n=18)	P value[1]
Age (years)	41 (14.5)	36.4 (11.3)	45.7 (16.2)	0.12
Sex (female)	29 (80.6%)	13 (72.2%)	16 (88.9%)	0.21
Percentage scalp hair loss by SALT score at baseline (%)	79.4 (28.3)	77.8 (31.0)	81.1 (26.1)	0.56
Pattern of scalp hair loss:				0.92*
AT	9 (25.0%)	4 (22.2%)	5 (27.8%)	
AU	12 (33.3%)	6 (33.3%)	6 (33.3%)	
Patchy	15 (41.7%)	8 (44.4%)	7 (38.9%)	
Baseline Scalp Hair Loss Score as measured by AASIS	8.656 (1.771)	8.188 (2.105)	9.125 (1.258)	0.27
Baseline Global Symptom Impact Score as measured by AASIS	0.391 (0.157)	0.401 (0.168)	0.380 (0.149)	0.76
Baseline Global Interference Score as measured by AASIS	0.321 (0.294)	0.327 (0.296)	0.314 (0.302)	0.88
Baseline AQoL-8D utility score	0.748 (0.209)	0.739 (0.207)	0.756 (0.218)	0.68
Comorbid Psychological Illness	2 (5.6%)	2 (11.1%)	0 (0)	0.99*
Depression	1 (2.8%)	1 (5.6%)	0 (0)	
Anxiety	1 (2.8%)	1 (5.6%)	0 (0)	

Data are means (SD) or numbers (%). *chi-squared test used

AA, alopecia areata; AT, alopecia totalis; AU, alopecia universalis

Table 2. Mean health utility of participants with AA as measured AQoL-8D by subgroup.

Subgroup	Mean (standard deviation)
Total	0.748 (0.206)
AT/AU	0.732 (0.256)
Patchy	0.773 (0.127)
Gender	
Female	0.738 (0.212)
Male	0.791 (0.174)
Age (Year)	
18 – 30	0.678 (0.231)
31 – 45	0.760 (0.160)
46 – 65	0.789 (0.210)

AT: alopecia totalis; AU: alopecia universalis