3.0 Abstract

Title: A Real World Study to Evaluate the Impact on Quality of Life and Psychosocial Factors Associated with Severe Psoriasis Following Treatment with Adalimumab

Keywords: Adalimumab, severe psoriasis, quality of life, psychosocial impact, observational study, prospective study.

Rationale and Background: Psoriasis is associated with a significant emotional and social impact that goes well beyond skin symptoms of the disease. In clinical practice it has been shown that patients with severe psoriasis have a greater prevalence of depressive symptoms, mood disturbances, anxiety and even suicidal ideation. Given the nature of the disease and the treatment failures which are required before a patient commences a biologic therapy such as adalimumab, the patient's mental health at initiation of biologics is an important consideration for clinicians. There is significant interest in assessing the impact of adalimumab on quality of life (QoL) and psychosocial factors in addition to skin symptoms.

Research Question and Objectives:

Hypothesis: The introduction of adalimumab for the treatment of psoriasis leads to a positive impact on psychosocial factors and disease-related quality of life.

Primary objective:

To assess change from baseline in patient reported Dermatology Life Quality Index (DLQI) measurement 16 weeks after initiating therapy with adalimumab in patients with severe psoriasis.

Secondary objectives:

- Assessment of change from baseline in QoL, clinician and patient reported disease severity (excluding DLQI) and patient reported factors relating to anxiety, depression, stress, sexual function and body image 16 weeks after adalimumab initiation.

Assessment of change from baseline in QoL, clinician and patient-reported disease severity (including DLQI) and patient-reported factors (as above) 4 weeks and 6 months after adalimumab initiation.

Study Design: A multi-centre, prospective, post-marketing observational study of patients with severe chronic plaque psoriasis commenced on adalimumab therapy in the UK. There were no interventions or changes to patient management for the study.

Setting: Dermatology departments in UK secondary and tertiary care NHS Trusts

Subjects and Study Size: A total of 153 patients were recruited into the study but no data were received for 10 patients (1 died pre-adalimumab initiation, 2 withdrew consent, 7 lost to follow-up or centre non-responsive), leaving a final sample size of 143.

Variables and Data Sources: Patient demographics and disease and treatment history data were extracted from patient medical records (paper and electronic) and dermatology departmental databases, as appropriate in each centre.

Prospective Data: The DLQI, Self-Administered Psoriasis Area Severity Index (SAPASI), Hospital Anxiety and Depression Scale (HADS), Cutaneous Body Image (CBI) scale, Short Form 12 (SF-12) Health Survey, Female Sexual Function Index (FSFI) (female patients) and International Index of Erectile Function (IIEF) (male patients) questionnaires were completed by patients prior to initiating adalimumab therapy (baseline) and at 4 weeks, 16 weeks and 6 months following initiation.

Results: Data were collected on 143 patients (63% male). Mean (M) age at diagnosis was 24 years and at adalimumab initiation was 45 years. DLQI scores improved significantly from baseline compared to 16 weeks ($M = 17.25$ versus $M = 4.51$, $p < 0.001$), as did PASI ($M = 16.98$ versus $M = 3.46$, $p < 0.001$) and SAPASI scores ($M = 21.02$ versus $M = 4.42$, $p < 0.001$). Significant improvements were also observed in 16 week CBI ($p < 0.001$), anxiety ($p < 0.001$) and depression ($p < 0.01$) scores and SF-12 mental ($p < 0.01$) and physical ($p < 0.001$) scores. Improvements were maintained at 6 months. Mean baseline score for the IIEF was comparatively higher (56/75) than the FSFI (16/36). Significant FSFI score improvements were only observed at 6 months ($p < 0.01$). No IIEF improvements were observed. PASI and SAPASI scores were significantly correlated ($r = 0.50$, $p < 0.001$).
Discussion: Patients were fairly representative of the general population of psoriasis patients in terms of age at diagnosis, and were similar to patients in previous observational studies of adalimumab in terms of gender distribution and mean age at adalimumab initiation. Patients in the study sample had severe psoriasis at initiation of adalimumab, and baseline patient-reported outcomes showed significant effects on QoL, body image and psychosocial wellbeing. Skin symptoms reduced significantly during treatment with adalimumab at 4 weeks, 16 weeks and 6 months following treatment initiation. 90% of patients were DLQI 'responders' at 16 weeks, suggesting that successful adalimumab treatment of the dermatological symptoms of psoriasis has a positive impact on patients' overall QoL. Adalimumab treatment was also associated with improvements in psychological wellbeing (anxiety, depression and CBI). Further, both anxiety and depression improved rapidly, which is novel to this study. The findings relating to the FSFI and IIEF may reflect the complex relationship between skin, image and sexual functioning and further study in this area would be warranted.
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