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AB1223 RHEUMATOID ARTHRITIS PATIENTS INCLUDED IN GLUCOCORTICOID TRIALS MOSTLY RESEMBLE THOSE SEEN IN OBSERVATIONAL COHORTS: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Background: Randomised controlled trials (RCTs) are considered the gold standard in clinical research. Their results, however, may not be generalizable to patients in routine care.¹ Together with methotrexate, glucocorticoids (GCs) constitute the mainstay of therapy for many patients with rheumatoid arthritis (RA), but it is unclear whether trial evidence is actually generalizable to real-world patients.

Objectives: This review assesses to what extent RA patients participating in GC-RCTs differ from RA patients taking GCs in routine care.

Methods: This study was registered with PROSPERO (CRD42019134675). MEDLINE was searched for RCTs and, as comparators, cohort studies in RA evaluating systemic GC therapy. Cohorts were not allowed to exhibit apparent selection mechanisms concerning gender or age. Random-effects meta-analyses combined descriptive baseline characteristics that may modify the benefit-risk-ratio of various RA therapeutics. Meta-analyses were stratified by study type (RCT and CS). Stratified estimates were subsequently compared.

Results: 55 RCTs and ten cohort studies (21,657 participants overall) were included. Twelve characteristics (related to general demographics and disease activity) were reported frequently enough to allow for comparative analysis. Compared to cohorts, RCT participants were younger (-4.7 [-7.2 to -2.1] years) and had somewhat higher erythrocyte sedimentation rates (12 [6 to 18] mm/h) (Table 1). In the other ten characteristics, estimates did not differ significantly. Numerically, cohort patients had more longstanding disease and slightly more favourable disease levels in core set variables. Comorbidities could not be assessed.

Table 1. Pooled estimates

Outcome	RCT	k	Cohort	k	Contrast	(95% CI)	p
General demographics							
Age (years)	54.2	50	58.9	10	-4.7	(-7.2 to -2.1)	<0.001
Female (proportion)	0.70	52	0.73	10	0.89	(0.68 to 1.16)	0.38
Current or previous smokers (proportion)	0.59	3	0.51	2	1.38	(0.61 to 3.14)	0.44
BMI (kg/m ²)	25.9	5	25.9	3	0.0	(-1.9 to 1.9)	0.98
Disease duration (months)	56.5	43	85.1	7	-28.6	(-85.6 to 28.4)	0.33
Disease activity							
ESR (mm/h)	40.1	31	28.2	3	11.8	(5.7 to 18.0)	<0.001
DAS	5.3	24	4.9	5	0.4	(-0.1 to 0.9)	0.12
RF+, (proportion)	0.67	32	0.63	6	1.19	(0.80 to 1.78)	0.39
ACPA+, (proportion)	0.64	7	0.56	3	1.38	(0.64 to 3.00)	0.41
HAQ	1.3	31	1.1	4	0.2	(-0.1 to 0.5)	0.15
Pain (0-10)	5.2	26	4.8	2	0.4	(-0.8 to 1.6)	0.52
Patient global assessment (0-10)	5.2	17	4.9	3	0.3	(-0.9 to 1.5)	0.58

Conclusion: The results of our study suggest that evidence from RA GC-RCTs can be generalized to most patients in routine practice. We note that comorbidities – a frequent exclusion criterion for trial participation – could not be evaluated due to insufficient reporting. Our findings contrast with a similar study on RCTs investigating biologics in RA: There, trial participants were found to differ significantly in 4 out of 8 investigated baseline characteristics.²

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AB1224 MAJOR DEPRESSIVE DISORDER AMONG CYPRIOT PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS AND CORRELATION WITH CLINICAL CHARACTERISTICS AND DISEASE-SPECIFIC HEALTH-RELATED QUALITY OF LIFE

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Background: Major depressive disorder (MDD) is a common comorbidity in patients with chronic rheumatic conditions, and patients with systemic lupus erythematosus (SLE) have an increased risk of developing depression. The coexistence of SLE and MDD might lead to impaired health-related quality of life (HRQOL). Gaining a deeper understanding of the factors associated with MDD in SLE will allow us to develop strategies in order to prevent depression and achieve an early diagnosis and management.

Objectives: The aim of this study is to determine the contributing factors associated with MDD in Cypriot SLE patients and examine the correlation between disease-specific HRQOL domains and depression.

Methods: We conducted a cross-sectional study of SLE patients who fulfilled the SLICC-2012 criteria. The patients were recruited from August 2019 to January 2020. Baseline demographic data, clinical features, and therapeutic regimens were captured. Depression was assessed by the patient health questionnaire (PHQ)-9, a validated tool to screen and diagnosed the condition. Scores above ≥10 are indicating MDD. HRQOL was evaluated by a disease-specific validated questionnaire, LupusQoL-Greek. LupusQoL scores ranged between 0-100, with higher scores reflecting better QoL. The self-rated health status was examined, and the response was separate to poor/fair vs excellent/good. Demographic data, LupusQoL domains, clinical and other features of the SLE patients were described and compared between MDD (PHQ-9 ≥ 10) and non-MDD (PHQ-9 < 10) groups using Wilcoxon ranksum tests for continuous variables and chi-square tests for categorical variables.

Results: A total of 88 SLE patients were included in the study, with a mean age of 48.6 (19-80), 71 (80%) were women, and mean disease duration of 13.2 years (0-44). Compared to the non-MDD group, patients with MDD (n=32, 36%) were significantly older (mean age 53.5 vs 46.9; p=0.03) and more likely to have the following SLE manifestations: mucocutaneous, vascular, pulmonary and musculoskeletal involvement. Furthermore, patients with MDD were less likely to be clinical quiescent (34.3%) compared with the non-MDD group (57.1%) (P<0.05). Self-rated health described as poor/fair was markedly associated with MDD (p<0.001). The LupusQoL domains' scores were notably lower in patients with MDD (PHQ ≥ 10), with a statistically significant reduction in all LupusQoL domains, indicating that depression was associated with worse HRQOL (Table 1).

Table 1. Differences in 8 LupusQoL domain scores among SLE patients with and without major MDD (PHQ-9 ≥ 10)

LupusQoL Domains (0-100)	PHQ-9 <10 (non-MDD)	PHQ-9 ≥10 (MDD)	P-value
Physical Health	72.87 (81.2, 9.3-100)	40.01 (32.75, 0-90.6)	<0.0001
Pain	75.27 (75, 16.6-100)	43.2 (41.6, 0-100)	<0.0001
Planning	81.08 (91.6, 0-100)	44.51 (50, 0-100)	<0.0001
Intimate relationship	68.38 (75, 0-100)	46.25 (50, 0-100)	0.0382
Burden to others	79.73 (83.3, 16-100)	51.97 (50, 0-100)	0.0003
Emotional health	81.76 (85.4, 25-100)	50.14 (50, 0-91.6)	<0.0001
Body image	84.09 (90.8, 5-100)	58.45 (66.6, 0-100)	0.0004
Fatigue	72.08 (75, 18.7-100)	41.2 (40.6, 6.2-81.2)	<0.0001