Background: Metabolic syndrome with low grade inflammation is associated with chronic diseases including osteoarthritis (OA) (1). Nonpharmacological treatment with a combination of an intensive diet and exercise produced better results in people with osteoarthritis (OA) than either treatment alone (2). We further developed the concept of an integrated lifestyle intervention in people with metabolic syndrome-associated osteoarthritis (MSOA) by combining a whole food plant-based diet with physical activity and stress management.

Objectives: To determine the effect of a multidisciplinary lifestyle program on pain, stiffness, and physical function in patients with MSOA.

Methods: In the “Plants for Joints” (PFJ) parallel-arm, randomized clinical trial, patients with MSOA were assigned to the PFJ group or the control group. Patients with metabolic syndrome (according to NCEP criteria) and OA in the knee and/or hip (according to clinical ACR criteria) were eligible for participation. The PFJ group followed a 16-week lifestyle program based on a whole food plant-based diet, physical activity, and stress management in addition to usual care. The control group received usual care.

Prior to the start of the study, it was hypothesized that the lifestyle program would lower pain and stiffness and improve physical function, based on the Western Ontario and McMaster Universities Arthritis Index (WOMAC) score (primary outcome), secondary outcome included anthropometrics, and metabolic markers. Patient partners selected the patient-reported outcome measures (PROMIS®) depression, fatigue, pain interference and physical function as additional secondary outcomes.

An intention-to-treat analysis with a linear mixed model, adjusted for baseline mean (SD) value of 55 for all the participants, fatigue improved 4 (95% CI 1 to 6; p = 0.03) in favour of the PFJ group. HDL and blood pressure decreased 0.18 mmol/l (95% CI 0.07 to 0.69; p = 0.02) and triglycerides by 0.32 (95% CI 0.07 to 0.57; p = 0.04) in favour of the PFJ group. DLB and blood pressure remained unchanged. Of the patient reported outcome measures (PROMIS®) only fatigue showed a significant improvement. Based on a baseline mean (SD) value of 55 for all the participants, fatigue improved with 4 (95% CI 1 to 6; p = 0.03) in the PFJ group when compared with the control group. Additional analyses adjusted for age, sex, and BMI did not lead to different outcomes.

No serious adverse events occurred.

Conclusion: The 16-week “Plants for Joints” lifestyle program substantially decreased pain and stiffness and improved physical function in people with MSOA. The lifestyle program may be beneficial in people with MSOA associated osteoarthritis of hip and/or knee.

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intermittent pain predicted beneficial effects of OLP, albeit the precision of the estimate was low. See Figure 1.

Fig 1. Forest plot showing the results of the subgroup analyses based on the intention-to-treat population with missing outcome data at week 9 replaced with the baseline observation (non-responder imputation). The outcome is change from baseline in KOOS pain at week 9 after 8 weeks of intervention. GLAD: The Good Life with osteoarthritis in Denmark exercise and education programme. OLP: Open-label placebo consisting of 4 intra-articular saline injections. K-L: Kellgren-Lawrence grading of radiographic disease severity. The full vertical line indicates the overall treatment effect, and the dashed line indicates zero effect. *24 GLAD and 26 OLP had no preference and are not included in the analyses, and 8 GLAD and 5 OLP had missing data; †For study knee.

Conclusion: These results imply that GLAD should not be considered as a one-size-fits-all intervention. For patients who take analgesics for their knee pain or report constant knee pain, GLAD seems to yield clinically relevant benefits when compared to an open-label placebo. The results support a stratified recommendation of GLAD as management of knee OA.

Disclosure of Interests: None declared

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New options in SLE-Sjogren and APS

POS0183 THE EFFECT OF BELIMUMAB ON SRI-4 RESPONSE IN MULTIPLE SUBGROUPS OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: RESULTS OF A LARGE INTEGRATED ANALYSIS


Methods: Belimumab (BEL) is approved for the treatment of active anti-Ro/SSA/RBC antibody-positive systemic lupus erythematosus (SLE).1 Four Phase 3 studies have consistently demonstrated greater SLE Responder Index (SRI) response rates with BEL vs placebo (PBO).2,3 This robust dataset allows for additional exploration of the onset of efficacy of BEL and response rates by patient (pt) characteristics.

Objectives: To perform a post hoc analysis evaluating the effect of BEL on SRI-4 response across a large, pooled population and pt subgroups.

Methods: The Belimumab Summary of Lupus Efficacy (Be-SLE) integrated analysis evaluated data from adults with SLE from 5 double-blind, PBO-controlled BEL trials: BLISS-SS, BLISS-SL, BLISS-NEA, BLISS-SC, and EMBRACE.2,4 Pts were randomised to BEL (monthly intravenous 10 mg/kg or weekly subcutaneous 200 mg) or PBO, plus standard therapy. Data were collected every 4 weeks (wks) from baseline (BL) to Wk 52. The SRI-4 response rate (a composite measure that includes ≥4-point reduction in SLE Responder Index, Safety of Estrogens in Lupus Erythematosus National Assessment - SLE Disease Activity Index [SELENA-SLEDAI] score, stable Physician Global Assessment [PGA] increase of <0.3, and no new British Isles Lupus Assessment Group [BILAG] 1A/2B organ domain scores) by visit and time to first SRI-4 response maintained through Wk 52 were determined for both treatment groups. SRI-4 response rates at Wk 52 were evaluated by BL characteristic subgroups: SELENA-SLEDAI score; SLE International Collaborating Clinics/American College of Rheumatology Damage Index (SDI) score; disease duration; biomarker levels (anti-dsDNA, complement [C3/C4]; glucocorticoid (GC), immunosuppressant (IS), and antimalarial (AM) use.

Results: Overall, 3086 pts were included (BEL, n=1869; PBO, n=1217). Most were female (94.4%); mean (standard deviation) SD age was 37.0 (11.6) years. Mean (SD) SLE duration was 6.4 (6.4) years. At Wk 52, in the overall population, significantly more BEL vs PBO pts were SRI-4 responders (Figure 1). A significantly greater proportion of SRI-4 responders was observed with BEL vs PBO as early as Wk 8 (38.4% vs 33.3%; odds ratio, OR [95% confidence interval, CI] 1.25 [1.07, 1.46]; p=0.0060), which continued to increase to Wk 52 (54.8% vs 41.6%; OR [95% CI] 1.70 [1.46, 1.98]; p<0.0001). At Wk 52, more BEL vs PBO pts had a 4-point reduction in SELENA-SLEDAI (56.3% vs 43.1%; OR [95% CI] 1.71 [1.47, 2.00]; p<0.0001), no worsening in PGA (76.6% vs 67.9%; OR [95% CI] 1.52 [1.28, 1.79]; p<0.0001), and no new BILAG 1A/2B organ domain scores (77.1% vs 69.4%; OR [95% CI] 1.47 [1.25, 1.74]; p<0.0001). Pts on BEL were 52% more likely to experience an SRI-4 response that was maintained through Wk 52 (hazard ratio, HR [95% CI] 1.52 [1.36, 1.69]; p<0.0001).

SRI-4 response rates were significantly higher with BEL vs PBO in most subgroups, with the highest response rates observed in pts with SELENA-SLEDAI score ≥10, low C3 and/or C4 + anti-dsDNA ≥30 IU/ml, and low C3 and/or C4 at BL (Figure 1).

Conclusion: Significantly more pts receiving BEL had SRI-4 response rates that occurred from Wk 8 and were maintained through Wk 52 compared with pts receiving PBO. The efficacy of BEL was consistent across multiple pt subgroups, with higher response rates in pts with SELENA-SLEDAI scores ≥10, low C3 and/or C4 + anti-dsDNA ≥30 IU/ml and low C3 and/or C4 at BL. These results further substantiate the benefits of BEL in the treatment of adults with SLE.

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POS0184 EFFICACY OF BIIB059 ON SKIN MANIFESTATIONS IN PARTICIPANTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) IN THE PHASE 2 LILAC STUDY (PART A)

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Methods: BiIB059 is a fully human monoclonal antibody that binds to and neutralizes IL-17.1 In Phase 2, LILAC study (commencing 29 May 2019; NCT04290081), pts (≥18 yrs) with active SLE with ≥1 skin manifestation were randomised 2:1 to receive BiIB059 (120 mg subcutaneous [SQ] injection every 4 weeks [Q4w]) or placebo (PBO) for 1 year and assessed through week 52.

Results: Of 170 pts, 114 (67.1%) were in the BiIB059 arm and 56 (32.9%) in the PBO arm; 107 (62.9%) were female (mean age 37.6 ± 11.6 yrs) and 63 (37.1%) were male (mean age 39.6 ± 11.7 yrs). The mean SELENA-SLEDAI score was 9.1 ± 5.0 and the mean cumulative prednisone dose was 6.6 ± 8.5 g. The key skin manifestations were lupus acrater, discoid lupus erythematosus, and subcutaneous nodules.

Conclusions:

"The results of LILAC study demonstrated that BiIB059 120 mg SQ Q4w was effective in reducing the severity of skin manifestations and other disease activity measures in pts with SLE who were active despite steroid use.

Disclosure of Interests: None declared

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