Conclusion: Our experience with RTX-B is limited; however, it represents an extensive report about the use of RTX-B in AAV patients and confirmed that it may be a well-tolerated and effective therapy in AAV setting, in agreement with previous evidence on RTX-O. Prospective and larger studies are needed to confirm this preliminary evidence.

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POS0254

EFFICACY OF APREMILAST IN THE TREATMENT OF ORAL ULCERS OF BEHÇET'S SYNDROME: RESULTS FROM THE EUROPEAN SUBGROUP OF RELIEF

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Background: Behçet's syndrome, a chronic, multi-system variable vessel vasculitis, is often characterized by painful oral ulcers (OU) affecting quality of life (QoL). Apremilast (APR), an oral PDE4 inhibitor, demonstrated efficacy in OU treatment in the phase 3 multinational RELIEF study.

Objectives: To evaluate APR efficacy in OU treatment in patients with active Behçet's syndrome in a prespecified subgroup of patients enrolled in 13 European RELIEF sites (France, Germany, Greece, and Italy).

Methods: patients were adults with active Behçet's syndrome and ≥3 OU at randomization or ≥2 OU at screening and randomization, without active major organ involvement. Patients were randomized (1:1) to APR 30mg BID or PBO during a 12-week double-blind phase. The primary endpoint was area under the curve for the number of OU through Week 12 (AUC_{Wk0-12}). Other outcomes were OU pain visual analog scale (VAS); achievement of OU complete response (ie, OU-free) and maintenance of OU complete response (ie, complete response at Week 6 and remaining OU-free for ≥6 additional weeks); OU partial response (ie, OU reduction ≥50%); disease activity (Behçet's Syndrome Activity Score [BSAS]; Behçet's Disease Current Activity Form [BDCAF], including Behçet's Disease Current Activity Index [BDCAI], and Patient's and Clinician's Perception of Disease Activity); and QoL (BDQoL; Short Form Health Survey version 2 [SF-36v2], including Physical Functioning [PF] scale and Physical and Mental Component Summary [PCS, MCS]).

Results: Of 207 patients randomized and treated in RELIEF, 52 were in the European subgroup. Mean (±SD) age in the subgroup was 39 (±12) years; 54% were women. Baseline disease characteristics were similar between treatment groups (Table 1). Patients receiving APR achieved lower AUC_{Wk0-12} for OU vs PBO (Figure 1) and greater reduction in pain. A greater proportion of patients receiving APR achieved complete, maintained, or partial OU responses at Week 12 vs those receiving PBO (Table 1). Consistent treatment effects favoring APR vs PBO were observed in disease activity, as shown by BSAS and BDCAF component scores at Week 12 (Table 1). Greater improvement in SF-36v2 MCS was observed favoring APR vs PBO at Week 12, and moderate treatment differences were seen for other QoL measures (BDQoL, SF-36v2 PF, and SF-36v2 PCS).

Conclusion: In the European subgroup of patients with Behçet's syndrome and OU in RELIEF, APR resulted in greater reduction in OU count, OU pain, and disease activity as well as favorable treatment effect on QoL measures than PBO.

These results are consistent with the efficacy of APR treatment in the overall RELIEF population.

Baseline Disease Characteristics, Mean*	PBO (n = 27)	APR (n = 25)	
Duration of BD, years	9.0	8.2	
OU count	3.8	4.0	
OU pain (VAS 0-100)	60.6	64.2	
BSAS (0-100)	38.7	41.4	
BDCAI (0-12)	3.5	3.6	
BDQoL (0-30)	10.5	9.0	
Efficacy Outcomes at 12 Weeks*	PBO	APR	Treatment
	(n = 27)	(n = 25)	Difference [95% CI]
OU pain (VAS 0-100), mean [†]	-17.7	-48.7	-31.0 [-44.7, -17.3]
OU complete response, n (%) [‡]	4 (14.8)	16 (64.0)	51.5 [29.8, 73.3]
OU maintained response, n (%) [‡]	1 (3.7)	8 (32.0)	26.7 [7.4, 46.0]
OU partial response, n (%) [‡]	11 (40.7)	21 (84.0)	46.0 [23.9, 68.0]
BSAS (0-100) ^{‡,§}	-5.23	-20.68	-15.5 [-22.6, -8.3]
BDCAI (0-12) ^{‡,§}	-0.0	-1.4	-1.4 [-2.2, -0.6]
Patient's Perception of Disease Activity ^{‡,§}	-0.4	-1.6	-1.2 [-2.1, -0.4]
Clinician's Overall Perception of Disease Activity ^{‡,§}	-0.6	-1.7	-1.0 [-1.7, -0.4]
BDQoL (0-30) ^{‡,§}	-1.25	-2.37	-1.12 [-3.8, 1.5]
SF-36v2 MCS (0-100) ^{‡,§}	-2.1	4.2	6.3 [2.2, 10.4]

*ITT population. [†]LS mean of the change from baseline at Week 12. [‡]Non-responder imputation for missing data. [§]LOCF approach. All efficacy endpoints (except BDQoL) were significant at the level of $P < 0.05$.

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Primary Endpoint: Area Under the Curve for the Number of OU From Baseline Through Week 12

$P < 0.05$; ITT population; error bars represent standard error. Multiple imputation used for imputing missing data.

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POS0255

IMPACT OF PLASMA EXCHANGE (PLEX) IN SEVERE ANCA-ASSOCIATED VASCULITIS (AAV): A REAL-LIFE DATA FROM A PROSPECTIVE COHORT

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Background: PEXIVAS was the largest clinical trial conducted on severe AAV patients and failed to demonstrate the contribution of PLEX on the prognosis of severe AAV. This data needs to be tested with real life experiences.

Objectives: The aim of this study was to explore the effects of PLEX on the prognosis of severe AAV in a real-life cohort.

Methods: Hacettepe University Vasculitis Research Center (HUVAC) prospective database was established in October 2014 by registering past and newly diagnosed patients. Baseline disease characteristics, treatments and survival status were recorded. For this study, patients with granulomatosis polyangiitis (GPA) and microscopic polyangiitis (MPA) who met the inclusion criteria of PEXIVAS trial [briefly; ANCA positive MPA or GPA patients with either severe renal involvement (necrotizing glomerulonephritis or active urinary sediment, and eGFR <50 ml/min) and/or severe pulmonary involvement (pulmonary hemorrhage due to active vasculitis)] at the disease onset were included. Patients were grouped whether they had PLEX or not. Demographic and disease-specific data and immunosuppressive agents used in induction phase were compared. Primary outcome was accepted as composite index of mortality or end-stage renal disease (ESRD) at the first year and at the final visit.

Results: Of 145 GPA and MPA patients, 49 patients had inclusion criteria and distribution of patients were as GPA (n=38), MPA (n=8) or renal-limited (n=3). 16 (32.6%) patients had PLEX. Median number of plasma exchange cycles was 6.5 (min-max; 2-12). Although severe pulmonary [10 (62.5%) vs. 5 (15.2%), p=0.001] and combined severe renal+pulmonary involvements were more prevalent [9 (56.3%) vs. 4 (12.1%), p=0.001] and baseline creatinine levels were higher in PLEX (+) group, BVAS and FFS scores were similar (Table 1). Induction immunosuppressive regimens were comparable.

At first year evaluation, primary composite outcome was observed in 11 patients (3 deceased, 8 ESRD) of PLEX (+) group whereas in 12 patients (2 deceased, 10 ESRD) of PLEX (-) group (p = 0.03, log-rank). In multivariate analysis: **combined renal+pulmonary involvements** (aOR: 6.5 [1.1-37.9]) and **serum creatinine** (for 1 mg/dl increment) (aOR: 1.3 [1.1-1.7]) were associated with primary outcome. In this model, having plasma exchange was not associated with a favorable outcome.

At the end of median follow-up [40.7 (1.2-170.3) months], outcome was observed in 12 patients (9 deceased, 3 ESRD) of PLEX (+) group and in 13 patients (6 deceased, 7 ESRD) of PLEX (-) group (p < 0.001, log-rank). In multivariate analysis: **having plasma exchange** (HR: 3.5 [1.4-8.5]) and **combined renal+pulmonary involvements** (HR: 2.4 [1.05-5.8]) were found as the predictors of primary composite outcome. In the figure 1, comparison of primary outcome according to FFS and plasma exchange status was given.

Conclusion: In real-life plasma exchange did not have a positive impact on the composite index of mortality and ESRD, similar to PEXIVAS trial. Presence of combined severe renal and pulmonary involvement was the predictor of worse outcome at 1-year and overall follow-up.

Table 1. Comparison of disease characteristics and composite indexes of patients

	PLEX (+) (n=16)	PLEX (-) (n=33)
GPA/MPA/Renal-limited (n)	12/3/1	26/5/2
Female, n(%)	8 (50.0)	13 (39.4)
Age at diagnosis, months (med,min-max)	54.5 (18.8-77.8)	55.6 (18.1-86.3)
MPO-ANCA / PR3-ANCA (n)	5 / 11	16 / 17
Follow-up duration, months (med, min-max)	16.6 (1.2-116.5)	50.5 (2.2-170.0)
BVAS at diagnosis, (med, min-max)	23 (14-37)	23 (8-33)
FFS ≥ 2 (n,%) (N=45)	23 (85.7)	26 (83.9)
Creatinine (mg/dl) at diagnosis ¹ (med,min-max)	8.1 (4.1-8.9)	3.1 (1.8-6.2)
CRP (mg/dl) at diagnosis (med,min-max)	21.8 (15.0-29.0)	11.5 (3.6-20.0)
Immunosuppressive (induction) (n,%)		
-Pulse steroid	14 (87.5)	29 (87.9)
-Rituximab	1 (6.3)	3 (9.1)
-Cyclophosphamide	12 (75.0)	28 (84.8)

¹p = 0.005

Figure 1. Comparison of primary outcome according to FFS and plasma exchange status

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Diagnostics and imaging procedures

POS0256

AUTOMATED CAPILLARY DETECTION AND IMAGE ANALYSIS SOFTWARE IN CAPILLAROSCOPY: CAPILLARY.IO

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Background: A nailfold capillaroscopy procedure is a non-invasive, low-cost, and well-established examination that can be used to diagnose several rheumatic autoimmune diseases and support the necessary follow-up of patients. There are two main elements to nailfold capillaroscopy: image acquisition and image interpretation. Both of these can present challenges: we need to ensure that the best possible images are captured, and we need to define the enlarged capillaries, capillary loss and pericapillary hemorrhages objectively. We introduce Capillary.io, an automatic image reading system able to recognize capillaries in images obtained with any microscope, generate automatic measurements of each capillary and take advantage of this information to report capillary morphology. Together it allows a comprehensive analysis that is capable of producing detailed reports for each patient.

Objectives: The primary outcome was general sensitivity and specificity, using images assessed by expert capillaroscopists as the gold standard.

Methods: 6500 images previously analyzed by capillaroscopists from GREC were compared with Capillary.io. Capillary morphology (enlarged capillaries, tortuosities, ramifications, megacapillaries, hemorrhages) of each of the capillaries contained in each of the images was analyzed manually by at least one expert capillaroscopist. Subsequently, the automatic image interpretation system was used to fully automatically analyze each of the capillaries contained in each image and the results obtained were compared.

Results: Overall, a total of 78.347 capillaries were compared, of which 47.734 were normal capillaries, 21.991 enlarged capillaries, 2672 megacapillaries, 8512 tortuosities, 1322 ramifications and 5149 hemorrhages. Capillary.io was able to detect 38.101 normal capillaries, 19.126 enlarged capillaries, 2389 megacapillaries, 5698 tortuosities, 718 ramifications and 3706 hemorrhages.