Conclusion: In our cohort of Italian BS patients the disease results slightly more prevalent in males. Gender-related differences were observed for posterior uveitis, DVP and papulopustular lesions which are more frequent in males, whereas EN-like lesions, arthralgia and intestinal involvement are more frequently observed in females. These data confirm that BS tend to be less aggressive in Italian female patients. No sex-differences were observed in HLA-B51 status.

Table 1. Clinical manifestations of male and female BS patients

Clinical Manifestations	Overall (285) n(%)	Male (168) n(%)	Female (117) n(%)	OR (95%CI)	p-value
OA	285 (100.0)	168 (100.0)	117 (100.0)	1.44 (0.00-9231)	NS
GU	171 (60.0)	95 (56.5)	76 (65.0)	0.70 (0.43-1.14)	NS
EN	138 (48.4)	69 (41.1)	69 (59.0)	0.48 (0.30-0.78)	0.0029**
Folliculitis	50 (17.5)	32 (19.0)	18 (15.3)	1.29 (0.69-2.44)	NS
Papulopustular lesions	194 (68.1)	140 (83.3)	54 (46.2)	5.83 (3.38-10.06)	0.0000**
Pathergy test	20 (45.5)	12 (7.1)	8 (6.8)	1.05 (0.41-2.65)	NS
Posterior uveitis	84 (29.5)	62 (37.0)	22 (18.8)	2.53 (1.44-4.42)	0.0010**
Anterior uveitis	51 (17.9)	29 (17.3)	22 (18.8)	0.90 (0.49-1.66)	NS
Panuveitis	24 (8.4)	17 (10.1)	7 (6.0)	1.77 (0.71-4.41)	NS
Episcleritis	4 (1.4)	2 (1.2)	2 (1.7)	0.69 (0.10-4.49)	NS
Arthralgia	114 (40.0)	53 (31.5)	61 (52.1)	0.42 (0.26-0.69)	0.0005**
Arthritis	74 (26.0)	44 (26.2)	30 (25.6)	1.03 (0.60-1.76)	NS
Deep venous thrombosis (DVT)	15 (5.3)	14 (8.3)	1 (0.9)	10.55 (1.37-81.35)	0.0054**
Superficial venous thrombosis (SVT)	33 (11.6)	18 (10.7)	15 (12.8)	0.82 (0.39-1.69)	NS
Neurological involvement	70 (24.6)	36 (21.4)	34 (29.1)	0.67 (0.39-1.15)	NS
Fatigue	72 (25.3)	37 (22.0)	35 (29.9)	0.66 (0.39-1.13)	NS
Fever	119 (41.8)	76 (45.2)	43 (36.8)	1.42 (0.88-2.31)	NS
Intestinal involvement	44 (15.4)	19 (11.3)	25 (21.4)	0.47 (0.24-0.90)	0.0208*
HLA-B51 positivity	186 (65.3)	114 (67.9)	72 (61.5)	1.32 (0.81-2.16)	NS

Abbreviations: n, number of subjects; OR, odds ratio; CI, confidence interval
statistically significant: *p<0.05; **p<0.01

Figure 1

REFERENCE

- [1] Leccese P, et al. *Curr Opin Rheumatol*.2017;29(1):12-16. [2] Hatemi G, et al. *Clin Exp Rheumatol*.2016;34 Suppl 102:10-22. [3] Pipitone N, et al. *Clin Exp Rheumatol*.2004;22(6 Suppl 36):S46-51.

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APREMILAST EFFECTIVENESS IN REFRACTORY ORAL AND GENITAL ULCERS OF BEHÇET'S DISEASE: DATA FROM REAL LIFE SETTINGS

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Background: Mucocutaneous lesions represent the earliest and the most frequent manifestations of Behçet's disease (BD), and may become disabling leading to substantial effect on quality of life. Recently the efficacy of the small molecule inhibitor of phosphodiesterase 4 apremilast in treating oral and genital ulcers has been shown in a phase 2 trial (1), whereas to date no results from real world data are available.

Objectives: The purpose of the present study was to describe our experience with apremilast in treating BD patients with oral and genital ulcers refractory to traditional therapies and previous biologic agents in real life settings

Figure 1

Methods: We retrospectively evaluated BD patients according to ICB (2) and/or ISG (3) criteria who had undergone apremilast therapy (30 mg twice daily) for oral and/or genital ulcers from November 2017 to January 2018 in four different specialized referral Units in Italy (Bari, Firenze, Potenza, Siena). Retrieved data including previous treatments were also collected. Our endpoint was to assess the number of oral and genital ulcers under apremilast treatment. Moreover pain due to ulcers was evaluated with a 100-mm visual-analogue scale (VAS), whereas disease activity was assessed by means of BDCAF score. Paired t-test or Wilcoxon matched-pair signed rank test, if applicable, were used for statistical analysis.

Figure 2

Results: Thirteen patients (9 females, 69.2%) with disease duration (mean $\pm$ SD) of 154.2 ± 167.7 months underwent apremilast treatment because of oral and genital ulcers inadequately responsive to previous immunosuppressant and/or biologic agents. At baseline, patients complained of 1 (1-1) (median (IQR)) oral and 0 (0-1) genital ulcers. At 3-month follow-up (data collected for 12/13 patients) the median number was 0 (0-1) for oral ulcers, and 0 (0-0) for genital ones, showing a significant improvement ($p=0.02$ for both). However, after 3 months, 3/12 patients (25%) stopped the treatment due to diarrhoea. Thereafter, at 6-month follow-up, a significant improvement of oral ulcers was observed (data collected for 8/13 patients, $p=0.03$), whereas a statistical significance for genital ulcers was not reached, even in the presence of a positive trend ($p=0.07$). A notable reduction in VAS and BDCAF scores was observed either after 3 months ($p=0.004$ and $p=0.02$, respectively) and 6 months ($p=0.01$ and $p=0.02$, respectively). The mean number of relapsing oral and genital ulcers during the first 3 months of therapy was significantly lower than that observed in the four weeks prior to apremilast ($p=0.01$ for both). Similarly, the average number of the sole oral ulcers appreciably decreased in the first 6 months of therapy ($p=0.03$). Notably no infections were reported during the whole observation period.

Conclusion: Our results, despite the small sample size, corroborate apremilast employment in real-life settings as viable treatment option in BD patients with mucosal involvement multi-refractory to standard treatments.

REFERENCES

- [1] Hatemi G, Melikoglu M, Tunc R, Korkmaz C, Turgut Ozturk B, Mat C, et al. Apremilast for behcet's syndrome-a phase 2, placebo-controlled study. *N Engl J Med* 2015;372:1510-8.
[2] International Team for the Revision of the International Criteria for Behcet's D. The international criteria for behcet's disease (icbd): A collaborative study of 27 countries on the sensitivity and specificity of the new criteria. *J Eur Acad Dermatol Venereol* 2014;28:338-47.
[3] O'Neill TW, Rigby AS, Silman AJ, Barnes C. Validation of the international study group criteria for behcet's disease. *Br J Rheumatol* 1994;33:115-7.

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