Objectives: To provide an update on opportunistic infections (OI) revised by an independent Safety Adjudication Committee (SAC) (3 paediatric rheumatologists and 2 paediatric infectious disease specialists).

Methods: The participating centres were asked to report all infections encountered by their JIA patients. PRINTO and the medical monitor (MM) classified events based on MedDRA dictionary. Moderate/serious/severe/very severe infections were then revised blindly by the SAC, who was asked to answer 6 questions. The events with consensus of at least 3/5 experts on the first 3 questions ('Is this an infection?', 'Is it common?', 'Is it opportunistic?') were retained for the analysis. With referral to the recommendations by Withrop *et al.*¹, for the first time a list of OIs in children with JIA on immunosuppressive therapy was elaborated and approved by consensus, through three Delphi steps. Finally, we compared the OI list defined by the SAC to the list of OI approved by the specialists.

Results: A total of 772 safety events related to 634 patients were submitted to the SAC. 689 (89.2%) events received consensus among the experts on the 3 questions and, of these, 682 (99.0%) were considered as infections, corresponding to 153 different Preferred Terms (PT), according to MedDRA dictionary. Among the 682 infections, 603 (88.4%) were defined by the experts as common and 119 (17.4%) as opportunistic. For 92 (60%) of the 153 PT, the MM and SAC used the same PT, while the remaining 40% was adjudicated by a third examiner, who analysed again the case reports and assigned the PT which was the most appropriate taking into account the experts' opinion. Among the final number of infections emerged that herpes viral, respiratory and EBV infections were the most frequent (Table). Analysing the infections by PT (n=149), the experts adjudicated: 22 as OI, 119 as not OI, 8 discordant. Comparing the experts' adjudication with the approved list of OI by PT, there was full agreement for the 22 PT classified as OI, while 19/117 (16.2%) PT resulted in the list, but were not classified as OI by the experts.

Abstract SAT0386 – Table 1. The most frequent HLT for the 682 infections with agreement of at least 3/5 experts on the first questions. (N: number of infections)

HLT	N	%
Herpesviral infections	265	38.9
Lower respiratory tract and lung infections	49	7.2
Upper respiratory tract infections	44	6.5
Epstein-Barr viral infections	38	5.6
Abdominal and gastrointestinal infections	32	4.7
Tuberculous infections	29	4.3
Bacterial infections NEC	27	4
Infections NEC	19	2.8
Ear infections	18	2.6
Candida infections	17	2.5
Influenza viral infections	14	2.1
Streptococcal infections	14	2.1
Salmonella infections	9	1.3
Urinary tract infections	9	1.3
Cytomegaloviral infections	8	1.2
Molluscum contagiosum viral infections	7	1
Papilloma viral infections	7	1
Sepsis, bacteraemia, viraemia and fungaemia	7	1
Campylobacter infections	5	0.7
Staphylococcal infections	5	0.7
Viral infections NEC	5	0.7
Escherichia infections	4	0.6
Pneumocystis infections	4	0.6
Skin structures and soft tissue infections	4	0.6

Conclusions: Our analysis showed a significant number of OI in JIA patients on immunosuppressants and provided an approved document stating the most frequent OI in children with JIA. The most frequent opportunistic pathogens resulted herpes virus, excluding varicella, and mycobacteria, but the list of definite and probable OIs needs to be validated/revised with the analysis of future datasets.

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SAT0387

DESCRIPTIVE ANALYSIS OF LEISHMANIASIS CASES IN THE FUENLABRADA OUTBREAK (SPAIN) ASSOCIATED WITH THE USE OF BIOLOGICAL THERAPY

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Background: Protozoan parasites of the genus *Leishmania* can cause opportunistic infections in patients using anti-tumour necrosis factor (anti-TNF) agents, and some authors recommend serological tests for leishmaniasis before using them. An outbreak of cutaneous and visceral leishmaniasis (CL/VL) occurred in the Fuenlabrada area (Spain) in 2010–2012. Some patients were on anti-TNF treatment.

Objectives: We aimed to explore leishmaniasis related to biological therapies in the literature, and to obtain data on leishmaniasis cases in patients using anti-TNFs referred to our Department of Infectious Diseases

Methods: Literature search of leishmaniasis cases in patients using biological therapies, and to realise descriptive analysis of the clinical features of patients treated with anti-TNFs in our outbreak.

Results: Cases detected in the literature, included our cases, are listed in table 1. In our outbreak of Leishmaniasis, 127 VL and 194 CL cases were detected. Six patients were using anti-TNFs: 2 presented with VL and were using etanercept (33.3%) and 4 using other anti-TNFs had CL (66.6%). (table 2) These results do not coincide with the total data (table 1): CL 55.2%, VL 44.8%, 17 ADA (44.7%), 16 IFM (42.1%), 4 ETN (10.5%), 1 CTZ (2.7%). There are not more cases described with another biologic therapies at the present time.

Abstract SAT0387 – Table 1

Pathology	Cutaneous Leishmaniasis	Visceral leishmaniasis
Rheumatoid Arthritis	4 ADA, 2 IFM, 1 CTZ	4 ADA, 4 IFM, 2 ETN
Psoriasis Arthritis	4 ADA, 1 IFM	1 ADA, 2 ETN
Ankylosing spondylitis	3 IFM, 3 ADA	2 IFM
Undifferentiated Arthritis		1 IFM
Giant cell arteritis		1 IFM
Pneumonia	1 ADM, 2 IFM	

Table 2

Hospital	Sex	Age	Condition	Anti-TNF	CL/VL	Other treatment	Clinical details
HUL	M	47	RA	CTZ	CL	MTX, folate acid.	Prior anti-TNF agents: - Infliximab (secondary loss of efficacy)
HUF	M	54	PSA	ETN	VL	MTX, SSZ (prior discontinued)	
HUF	F	61	PSA	ADA	CL	Prior: EFA, ETN, MTX, SSZ (prior discontinued)	Prior anti-TNF agents: EFA, ETN (adverse event)
HUF	F	64	RA	ADA	CL	MTX (discontinued)	Non-neutropenic granulomatous disease
HUF	M	32	PSO (not rheum.)	IFM	CL	MTX, CSA, A. chetini	
HUF	F	55	RA	ETN	VL	MTX, PRED	ETN and MTX discontinued 1 month before myelodysplasia syndrome

HUL: Hospital Infanta Leonor; HUF: Hospital Universitario de Fuenlabrada; RA: Rheumatoid arthritis; AS: ankylosing spondylitis; PSA: Psoriasis arthritis; FFA: Fungal arthritis; ADA: adalimumab; ETN: etanercept; EFA: efalizumab; MTX: methotrexate; CTZ: certolizumab pegol; SSZ: sulfasalazine; CSA: Cyclosporine A

Conclusions: This preliminary detection of leishmaniasis in patients using anti-TNFs is aimed at examining the safety of TNF α inhibitors in areas where Leishmania is endemic. This is a small series, but the largest described to date. Our preliminary results suggest that the use of either TNF α receptor or other anti-TNFs has the same probability of triggering the disease but etanercept seems to be associated with fewer, although more severe, cases of VL. Nevertheless, adding all the cases, Table number 1, ADA e IFM are the 86.8% of the Leishmaniasis, but perhaps will be due to this therapies are combined and of the most prevalent use. On the other hand, no leishmaniasis cases related to IBD treatment have been described in the literature, suggesting possible involvement of therapies concomitant with the use of anti-TNF with MTX. We detected 3 additional cases of VL and 1 CL using MTX without anti-TNFs. Serological tests for leishmaniasis before using anti-TNFs might not be useful.

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