DATA MATTERS: keeping track of your health information

OP0302-PARE THE INTERNATIONAL MAP OF AXIAL SPONDYLOARTHRITIS GLOBAL REPORT: SUPPORTING THE INCLUSION OF THE PATIENT PERSPECTIVE IN POLICY AND CLINICAL PRACTICE

Keywords: Lifestyles, Real-world evidence, Quality of life

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Background: Axial spondyloarthritis (axSpA) is a chronic inflammatory rheumatic musculoskeletal disease that can lead to chronic pain, structural damage, and disability. It often has a significant physical impact, causes psychological distress and can disrupt every aspect of a patient's life. While scientific research in axSpA has grown significantly, the patient perspective remains insufficiently explored and the disease burden continues to be underestimated. The International Map of Axial Spondyloarthritis (IMAS) is a research initiative of the impact and burden of axSpA from the patient perspective, identifying the unmet needs of axSpA patients and exploring impact beyond solely the physical symptoms.
Objectives: By producing an accessible global report on the results of IMAS, ASIF aim to provide its member organisations with much needed, robust evidence of the impact of the disease. The report will be used to raise awareness of the reality of axSpA, particularly amongst healthcare providers and policy makers; with the intention of incorporating the patient perspective much more into clinical practice and policy. The report also provides patients and their carers with a better insight into axSpA experiences around the world.
Methods: This research is a collaboration between the Axial Spondyloarthritis International Federation (ASIF), the University of Seville and Novartis Pharma AG. ASIF and its members have supported recruitment of survey participants from 27 countries across Europe, Asia, North, Central and South America, and Africa. In total 5,557 people completed the survey, providing a unique insight into how axSpA effects daily life. IMAS collected information through a comprehensive questionnaire of over 120 items on socio-demographics; behaviour; disease diagnosis and characteristics; comorbidities; psychological distress; healthcare utilization; treatments; disease activity; physical activity and limitations; working life; relationships; and the hopes and fears of patients. The ASIF IMAS sub-committee reviewed the global dataset results and agreed the scope of the global report. The IMAS scientific committee also reviewed the result, identifying key findings. ASIF held webinars with its members to seek their feedback on the results; asking them how they would use such a report how it can support their work.
Results: 5,557 axSpA patients participated in IMAS. The mean age was 43.9 years, 55.4% were women, 46.2% had university education, and 48.5% were employed. 20.6% were on sick leave (temporary or permanent), 71.4% had difficulty finding a job due to axSpA, and 71.0% reported work-related issues. Patients' mean diagnostic delay was 7.4 years, disease activity measured by the BASDAI was 5.4 (out of 10), and risk of poor mental health measured by the GHQ-12 was identified in 59.4% of respondents. In addition, patients had a mean of 2 physical comorbidities. The report, which will be translated into a number of languages, includes data on all topics that were collected by IMAS. But at the request of our members, it focusses on the journey to diagnosis; physical and mental health; daily life impact; accessing treatment and care; and hopes and fears. Gender and regional differences are reported on in each of the chapters.
Conclusion: IMAS has shown the global profile of axSpA patients, quantifying and highlighting unmet needs, including unacceptable delay in diagnosis, high disease activity, work-related problems, and poor mental health in axSpA patients worldwide. The global report on IMAS will provide ASIF's members with empirical evidence of the impact of axSpA on a person's life in order to support their awareness and advocacy work. IMAS was recognised when it won the EFPIA Connecting Healthcare 2021 Awards for its ability to bring patients and medical professionals together in an initiative aimed at improving the quality of life of people living with axSpA from around the world.
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OP0303-PARE MULTI-STAKEHOLDER CO-CREATION TO FACILITATE CLINICAL TRIAL RECRUITMENT - A FEASIBILITY STUDY

Keywords: Clinical trials, Patient information and education

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Background: Recruitment for clinical trials remains a hurdle, causing potential delays in bringing innovative treatments to patients. Furthermore, there is not much communication about clinical trials towards the patient population and the general population has a lot of misconceptions around clinical trials. Communication about clinical trials is also subjected to a strict regulatory framework, especially in Europe. The information that can be found online is often in English and difficult to understand for the lay public.
Objectives: For this reason, a feasibility study has been performed to develop a clinical trial portal for Belgium that allows users to search for trials in a local and lay language, while offering the portal to patient organisations and hospitals to receive updates on newly initiated trials.
Methods: During the feasibility study the following aspects have been analysed by organising multi-stakeholder workshops, involving patient representatives and patient organisations (20), hospitals (8), HCPs (14), industry and representatives (10) of the Belgian medicines agency:user expectations, technical considerations, legal restrictions, regulatory and compliance aspects. Based on the multi-stakeholder workshops, a prototype has been developed that has been tested via user validation workshops. For the field of rheumatology, ReumaNet has represented the RMD community.
Results: The result of the feasibility study revealed that only 15% of patient organisations (out of 190) mention clinical trials on their website, out of 140 websites of hospitals, only 16% mention clinical trials, while 2% have a search engine to search for ongoing studies. All academic hospitals (7) had a section dedicated to trials on their website. There was a great interest from the patient community (over 20 PAG participants) and the HCP representatives. A legal analysis has also set a framework for compliant communication about clinical trials to the lay public as well as a GDPR framework to define privacy related aspects of the portal.The portal has been launched in September 2022 as a first version, an improved version with a PAG dashboard is launched in February 2023.
Conclusion: Based on the feasibility study, a clear need was identified to further develop the clinical trial portal in co-creation with the various stakeholders.
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ANCA-associated vasculitis

OP0304 BENRALIZUMAB FOR EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA): RESULTS FROM A EUROPEAN MULTICENTER STUDY ON 121 PATIENTS

Keywords: Real-world evidence, bDMARD, Vasculitis

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Background: Eosinophilic granulomatosis with polyangiitis (EGPA) is an ANCA-associated vasculitis characterized by asthma, ear-nose-throat (ENT) manifestations, peripheral hypereosinophilia and systemic vasculitic involvement [1]. Increased serum levels of interleukin 5 (IL-5) have been observed in eosinophilic disorders, including EGPA, and a genome-wide association study identified the IL-5 region as a major EGPA-associated loci [2]. On these bases, an increasing interest is focusing on benralizumab (an IL-5 receptor antagonist approved for severe eosinophilic asthma at the dosage of 30mg every 4 weeks for 3 administrations, then every 8 weeks) as a new potential therapy for EGPA. Following the promising results of a pilot study on 10 patients [3], a randomized double-blind trial is ongoing to assess the efficacy and safety of benralizumab at a higher dosage (30mg/4 weeks), as compared to mepolizumab (another IL-5 inhibitor approved for EGPA) in patients with EGPA (NCT04157348). In the meanwhile, isolated cases of patients with refractory EGPA, successfully treated with benralizumab, have been described in the literature [4,5].
Objectives: This study aimed to assess the efficacy and safety of benralizumab in a multicenter European cohort of patients with EGPA.
Methods: The study included patients with EGPA treated with benralizumab at 28 centers belonging to the European EGPA Study Group. Efficacy and safety outcomes were assessed after 3, 6 and 12 months of treatment. Complete response (CR) was defined as no disease activity (Birmingham Vasculitis Activity Score [BVAS] = 0) and a daily prednisone equivalent dose ≤4 mg. Respiratory outcomes included asthma, ENT manifestations and lung function.
Results: A cohort of 121 patients with EGPA was included. All were treated with benralizumab at the dosage approved for eosinophilic asthma (30mg every 4 weeks for 3 administrations, then every 8 weeks). The proportion of patients meeting the criteria for CR was 16% at 3 months, 26% at 6 months and 46% at 12 months of follow-up (**Table 1**). During follow-up, a drop in BVAS was recorded, from a median score of 3 (IQR 2-8) at baseline to 0 (0-2) at month 3 and 6 and to 0 (0-1) at month 12 (p<0.001 at all timepoints). Regarding respiratory outcomes, the proportion of patients reporting active asthmatic decreased from 94% at baseline to 39% at 3 months (p<0.001), and that of patients with active ENT manifestations decreased from 70% at baseline to 49% at 3 months (p<0.001), with concomitant improvements in lung function. 19 patients experienced adverse events, three requiring hospitalization.
Conclusion: The results from this large European real-world study suggest that benralizumab, at the dosage approved for severe eosinophilic asthma, could be effective and safe to control respiratory EGPA manifestations and overall disease activity.
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Table 1. Efficacy outcomes

	Benralizumab 3 months beginning (t0)		p-value (t3 vs t0)	6 months	p-value (t6 vs t0)	12 months	p-value (t12 vs t0)
N patients	*121*	*121*		*101*		*85*	
Complete response	-	15/96 (15.6%)		23/87 (26.4%)		32/69 (46.4%)	
BVAS, median (IQR)	3 (2-8)	0 (0-2) [n=96]	<0.001*	0 (0-2) [n=87]	<0.001*	0 (0-1) [n=69]	<0.001*
Respiratory involvement							
Pulmonary	114 (94.2)	43/111 (38.7)	<0.001*	36 (35.6)	<0.001*	33 (38.8)	<0.001*
ENT	85 (70.3)	54/111 (48.6)	<0.001*	46 (45.5)	<0.001*	40 (47.1)	<0.001*

BVAS= Birmingham Vasculitis Activity Score; ENT= ear-nose-throat; IQR= interquartile range.

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OP0305 THE BURDEN OF MULTIMORBIDITY IN ANCA-ASSOCIATED VASCULITIS: A COHORT STUDY

Keywords: Comorbidities, Vasculitis, Epidemiology

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Background: With improvements in the risks of relapse and mortality in ANCA-associated vasculitis (AAV), a better understanding of disease- and treatment-related complications in people with AAV is necessary to optimize outcomes and personalize care. Multimorbidity (MM) is a patient-centered approach to measuring complications and is defined as the presence of multiple chronic conditions[1]. MM is associated with risk of death and quality of life in other conditions. MM remains poorly understood in AAV[2].
Objectives: To determine the burden of multimorbidity in AAV.
Methods: We used the 2002-2019 Mass General Brigham (MGB) AAV cohort: an inception cohort of consecutive MPO- or PR3-ANCA+ incident AAV cases at a multi-center healthcare system in New England, USA. Comparators without systemic rheumatic disease were identified from MGB and matched to cases (10:1 ratio) by encounter date, age, sex, and race. We adapted a definition of MM as the presence of ≥ 2 of 37 chronic conditions, identified by use of ICD-9/10 codes ≥ twice over ≥ 30 days[1]. Manifestations of AAV (e.g., kidney disease) were excluded from the MM definition. Conditions present ≥ 6 months prior to the index date (date of treatment initiation) were excluded. First, we determined the proportion of cases and comparators with MM using the Aalen-Johansen method, accounting for the competing risks of death and loss to follow up. Second, we used Cox proportional hazard models to estimate the hazard ratio (HR) of MM in cases vs comparators and restricted mean survival time to estimate days free of MM in cases vs comparators. Third, we used latent class analysis to characterize clusters of morbidity among people with MM.
Results: There were 547 cases matched to 5,259 comparators (Table 1); mean age was 59 years and the majority were female (61%) and white (88%). Median follow-up in cases and comparators was 102 months and 66 months, respectively. MM was substantially more common in cases vs comparators and AAV cases had nearly an 8-fold higher risk of MM vs comparators (Figure 1, HR 7.6, 95% CI 6.6-8.7). Over 5 years, each case had an average of 707 fewer days with MM than comparators (963.4 vs 1670.5 days, p<0.001). At 1 year, two clusters of MM in AAV were identified with 76% and 24% captured in Clusters 1A and 1B, respectively. Hypertension and hyperlipidemia were common in Cluster 1A whereas Cluster 1B was characterized by painful conditions (e.g., headache, back pain, GERD). At 2 years, two clusters were identified with 82% and 18% captured in Clusters 2A and 2B. Cluster 2B was distinguished from 2A by a high burden of cardiovascular (CV) and pulmonary disease along with typical CV risk factors. At 5 years, three clusters were identified with 81%, 11%, and 8% captured in Cluster 5A, 5B, and 5C. Morbidities most common in Cluster 5A were hypertension and hyperlipidemia. Cluster 5B was distinguished by a higher burden of CV and pulmonary disease whereas Cluster 5C had the highest burden of certain glucocorticoid toxicities (e.g., osteoporosis, obesity, hypertension).
Conclusion: AAV is associated with a high burden of MM and carries a greater risk of MM than the general population. MM in AAV is characterized by clusters defined by morbidity burdens that vary over disease course and reflect a high impact of disease and its treatment. The development of interventions to prevent MM and minimize its impacts are needed. These findings identify an important