Respondents were asked about use of a digital tool to support lifestyle behaviour change. Over 3/4 were open to using digital tools. Regarding the respondents' preferences: the top three preferences were for reminders, contact with peers and information on the importance of changing the behaviour in question.

Conclusions: The survey suggests that SRA members have digital access despite 1/3 being older than 65. The focus for current and future behaviour change is physical activity and to a lesser extent, healthy eating. Smoking and risky alcohol use behaviours are low in this group. Willingness to engage in a digital tool is high, and preferences are clear, with interest in human contact with professionals and peers through the digital tool, as well as automated functions.

Disclosure of Interest: None declared

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FRIDAY, 15 JUNE 2018

Advances in biologic therapy of small vessel vasculitis

OP0332 PAEDIATRIC OPEN-LABEL CLINICAL STUDY OF RITUXIMAB FOR THE TREATMENT OF GRANULOMATOSIS WITH POLYANGIITIS (GPA) AND MICROSCOPIC POLYANGIITIS (MPA)

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Background: Rituximab in combination with glucocorticoids (GC) is approved to treat adult patients (pts) with GPA or MPA; however, limited data exist on the safety and efficacy of rituximab in paediatric pts with these potentially life- and organ-threatening diseases.

Objectives: To report the interim safety, pharmacokinetics (PK) and exploratory efficacy data from the 6 month remission induction phase of a Phase IIa international, open-label, 18 month clinical study of rituximab in paediatric pts with GPA or MPA.

Methods: Pts aged ≥2 to≤18 years with newly diagnosed or relapsing GPA/MPA received 4 intravenous (IV) rituximab infusions of 375 mg/m^2 body surface area (BSA) on Days 1, 8, 15 and 22 with concomitant GC 1 mg/kg/day (max 60 mg/day) tapered to 0.2 mg/kg/day minimum (max 10 mg/day) by Month 6. All pts received 3 doses of pulse IV methylprednisolone (30 mg/kg/day, max 1 g/day) prior to first rituximab infusion and mandatory prophylaxis for *Pneumocystis jiroveci* infection. Pts were also pre-medicated with acetaminophen and an antihistamine, 1 hour before each rituximab infusion. Adverse events (AEs) and laboratory data were measured at each study visit (1, 2, 4 and 6 months). Plasma samples for PK analysis were collected throughout the study; clearance and area under the curve (AUC) were calculated using population PK modelling from the RAVE study of rituximab in adult pts with GPA/MPA.[1] For exploratory efficacy assessment, the Paediatric Vasculitis Activity Score (PVAS) was measured at each study visit.

Results: Of the 25 pts enrolled, 19 (76%) had GPA and 6 (25%) had MPA (median [range] age 14[6–17] years; 80% female). Median (range) disease duration was 0.5 (0.2–0.72) months; 2 pts had received prior cyclophosphamide therapy. All received 4/4 rituximab infusions and completed the 6 month induction phase. By Month 6, all pts had experienced ≥1 AE. The most common AEs by system organ class were infections and infestations in 16 pts (64%). AE terms reported in ≥3 pts are listed in the table 1. Eleven serious AEs occurred in 7 pts (28%), including 3 serious infections (viral gastroenteritis, one lower and one upper respiratory tract infection). 32% of pts had ≥1 infusion related reaction (IRR). No serious IRRs or deaths were reported. The relationship between AUC and BSA was flat and comparable to adult pts. A total of 13 pts (52%) achieved remission by 6 months, defined as PVAS of 0 and GC dose 0.2 mg/kg/day (max 10 mg/day) or PVAS of 0 on 2 consecutive readings≥4 weeks apart irrespective of GC dose.

Abstract OP0332 – Table 1 Adverse events reported in ≥3 patients

Adverse event	Number of events (% of pts with ≥ 1 AE)
Headache	6 (24%)
Upper respiratory tract infection	5 (20%)
Abdominal pain (upper)	3 (12%)
Back pain	3 (12%)
Blood IgG decreased	3 (12%)
Chest pain	3 (12%)
Cough	3 (12%)
Epistaxis	3 (12%)
Hypertension	3 (12%)
Nausea	3 (12%)
Pyrexia	3 (12%)
Vomiting	3 (12%)

AE, adverse event; IgG, immunoglobulin G.

Conclusions: In the initial 6 months of this first global clinical trial of rituximab in paediatric pts with GPA/MPA, rituximab was generally safe and well tolerated. The overall safety profile and PK parameters were comparable to adults with GPA/MPA. No new safety signals were observed. However, the study size and interim nature of the analysis limit firm conclusions. The clinical trial and additional efficacy, PK and safety analyses are ongoing.

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OP0333 SURVIVAL IN ANCA ASSOCIATED VASCULITIDES: A RETROSPECTIVE MULTICENTRIC ANALYSIS IN NORTHERN ITALY

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Background: Patients affected by ANCA associated vasculitides (AAV) show lower survival than general population, even if the mortality decreased significantly in the last decade.

Objectives: Aim of our study is to analyse the early mortality (within 6 months) and the long-term survival in a multicentric Italian cohort of AAV patients.

Methods: we identified all patients affected by AAV, diagnosed from 1995 until 2017, followed routinely in four vasculitis referral centres in Norther Italy. We enrolled patients with diagnosis of granulomatosis with polyangiitis (GPA) and micro polyangiitis (MPA), fulfilling EMA algorithm or [CHCC 2012] definitions, with complete survival data at last follow up. The analysis focused on early mortality, long-term survival and their predictors.

Results: We enrolled 200 AAV patients (F/M 110/90, Caucasian 98%) with a median age at diagnosis of 54.6±15.2 years. 157 (78.5%) were affected by GPA and 43 (21.5%) by MPA. Data about ANCA antibodies were available in 181 patients and 157 (87%) resulted ANCA positive: 100 c-ANCA/PR3, 56 p-ANCA/MPO and one with double specificity PR3-MPO-ANCA.

During the follow up period [53[28–100] months], we registered 21 (10.5%) deaths, 6 (28.5% of all mortality) within 6 months after diagnosis: 9 patients died due to infectious complications, 1 due to hepatic cancer, 1 due to end stage heart failure, 1 due to massive cholestasis and 9 due to unknown causes.

Early mortality was significantly associated with a higher frequency of alveolar haemorrhage (p=0.01; OR 11.1 IC95% 2.1–60.1) and respiratory failure (p<0.001, OR 28.3 95% CI: 4.7 to 170.6).

The long-term survival, analysed with Kaplan-Maier method, did not show significant differences between GPA and MPA patients, while a significant poorer

survival was observed in p-ANCA/MPO patients than c-ANCA-PR3 and ANCA negative patients (Log rank test: p=0.04).
At univariate analysis of baseline data, deceased patients resulted older at disease onset (p=0.001) with more comorbidities (p<0.001) and presented at diagnosis a higher frequency of respiratory failure (p=0.002, OR 7.1 IC95% 2.2–22.2) and renal insufficiency (p=0.003, OR 4.7 95% CI: 1.6 to 13.7). No significant differences were noted in term of infections/year, relapses/year and cancer development.
Conclusions: In this large cohort of Italian patients we confirm a higher short and long-term survival in AAV patient than reported in literature. Nevertheless, up to one third of deaths occurred within 6 months after diagnosis and infection diseases resulted the most frequent cause of death. Moreover, our data confirm the prognostic importance of ANCA pattern and the poor outcome of patient with severe lung and renal involvement.
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FRIDAY, 15 JUNE 2018: Tapering and flaring in PsA and SpA

OP0334 EFFICACY AND SAFETY OF CONTINUING VERSUS WITHDRAWING ADALIMUMAB (ADA) IN MAINTAINING REMISSION IN PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA)

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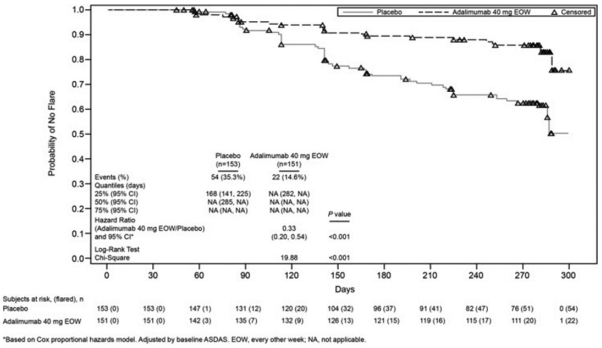
Background: It is not known whether TNF blockers can be stopped in nr-axSpA patients (pts) who are in remission.
Objectives: ABILITY-3, reported here, assessed if ADA can be discontinued or should be continued in nr-axSpA pts in sustained remission after a 28-wk open-label period.
Methods: ABILITY-3 enrolled adult pts diagnosed with nr-axSpA, fulfilling ASAS criteria but NOT modified New York criteria who had objective evidence of active MRI inflammation in the SI joints or spine or elevated high-sensitivity CRP at screening, active disease at baseline (ASDAS ≥2.1, BASDAI≥4, total back pain ≥4), and inadequate response to ≥2 NSAIDs. Pts who achieved ASDAS inactive disease (ASDAS <1.3) with open-label ADA 40 mg every other wk at wk 16, 20, 24, and 28 were randomised to 40-wk, double-blind PBO (withdrawal) or ADA (continuation) in period 2. Primary efficacy endpoint was proportion of pts who did not experience a flare (ASDAS ≥2.1 at 2 consecutive study visits) during period 2. Secondary endpoints were also assessed up to wk 68 (nonresponder imputation).
Results: Of 673 enrolled pts, 305 (45%) were randomised to double-blind treatment. A significantly greater proportion of pts treated with ADA vs PBO had no flares (70% vs 47%; p<0.001) at wk 68; relative risk of flare with treatment withdrawal was 1.77. Time to flare analysis showed significantly lower risk of flare for ADA vs PBO (figure 1). At wk 68, significantly greater proportions of ADA vs PBO pts achieved secondary endpoints, except for HAQ-S (table 1). Among pts who received ADA at any time, 77% reported adverse events (AEs) and 4% reported a serious AE; nasopharyngitis (17%), upper respiratory tract infection (12%), worsening of axSpA (9%), headache (8%), and diarrhoea (6%) were the most common. During period 2, incidence of AEs was similar for ADA and PBO (65% vs 69%), incidence of serious AEs was higher for PBO vs ADA (7% vs 1%), and the most common AEs in both the ADA and PBO groups were nasopharyngitis (16% vs 13%), upper respiratory tract infection (13% vs 8%), and worsening of axSpA (6% vs 14%; none serious).

Abstract OP0334 – Table 1 Efficacy outcomes at week 68

Wk 68, n (%)	ADA (40 mg EOW) n=152	PBO n=153	*P* Value
No flare	106 (70)	72 (47)	<0.001
ASDAS ID	87 (57)	51 (33)	<0.001
ASDAS MI	89 (59)	49 (32)	<0.001
ASDAS CII	102 (67)	69 (45)	<0.001
ASAS20	107 (70)	72 (47)	<0.001
ASAS40	100 (66)	70 (46)	<0.001
ASAS 5/6	87 (57)	49 (32)	<0.001
ASAS PR	64 (42)	41 (27)	0.005
BASDAI50	103 (68)	72 (47)	<0.001
Change from baseline in BASFI, LSmean±SE	–3.97±0.11 n=111	–3.51±0.13 n=77	0.007
Change from baseline in HAQ-S, LSmean ±SE	–0.68±0.04 n=112	–0.58±0.04 n=79	0.088



Abstract OP0334 – Figure 1 Time to flare by week 68

Conclusions: In pts with nr-axSpA who achieved sustained remission with ADA, continued therapy was associated with significantly more pts maintaining remission and lower disease activity than treatment withdrawal. These results support the continuation of ADA therapy after achievement of sustained remission. Safety findings were consistent with established safety profile of ADA.
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OP0335 HIGH NEED FOR ANTI-TNF THERAPY AFTER WITHDRAWAL STRATEGY IN EARLY PERIPHERAL SPONDYLOARTHRITIS

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Background: Treatment with TNFi in early stages of peripheral Spondyloarthritis (pSpA) results in higher rates of clinical remission, compared to treatment in more longstanding disease.[1] When remission is reached, the recently updated T2T-recommendations suggest tapering of treatment. In the CRESPA-trial pSpA patients were treated with golimumab monotherapy; we demonstrated that – after reaching sustained remission – discontinuation of golimumab led to biological-free remission in 53% of patients; conversely 47% experienced a disease flare. It is currently unknown if concomitant administration of DMARDs could lead to higher rates of biological-free remission.
Objectives: To explore – in pSpA patients in clinical remission – the possibility that co-medication with methotrexate would allow discontinuation of the TNFi.
Methods: The CRESPA-trial included patients with active pSpA and symptom duration <12 weeks; the primary study results have been reported previously (reference). In the CRESPA-Extension protocol, patients were included that either did not reach remission (but had substantial improvement with golimumab treatment), or that experienced recurrence of arthritis, enthesitis or dactylitis within 1 year after discontinuation of golimumab. These patients received additional open-label golimumab 50 mg SC every 4 weeks for 2 years. At week 104, patients were offered an additional 12 weeks of golimumab treatment, but now in combination with methotrexate 15 mg weekly. At week 116, patients in clinical remission continued methotrexate, but discontinued golimumab. Patients were prospectively followed to assess the rate of sustained biological-free clinical remission. In