predicted). Primary outcome was to compare the change in FVC after 6 months of therapy with MMF or placebo. Secondary outcomes were change in SF-36v2, Mahler dyspnoea index (MDI) and adverse events profile of MMF and placebo.

Methods: This was a double-blind, randomised, placebo-controlled trial conducted at a tertiary care centre in north India. SSC-ILD patients with FVC $\geq 70\%$ and aged >18 years were randomised to receive either MMF (up to 2 g/day) or placebo for 6 months. FVC, DLCO, MRSS, SF36v2, MDI and 6 min walk distance (6MWD) were noted at baseline and 6 months. Outcome was categorised into improved/stabilised (any increase in FVC or fall in FVC $<10\%$ from baseline) and worsened (fall in FVC $\geq 10\%$ from baseline). Trial was approved by the institute ethics committee and was registered at ClinicalTrials.gov (NCT02896205).

Results: Forty-one subjects were included in the study (20 MMF and 21 placebo). Mean age was 40.3 ± 10.1 years and 95.1% were females. Median duration of illness was 5 years (IQR: 3–9). Mean baseline FVC was $81.71 \pm 9.35\%$, DLCO was $50.36 \pm 14.24\%$, MDI was 7.68 ± 2.72 , 6MWD was 423.61 ± 61.64 m, MRSS was 17.07 ± 8.36 . Fifteen subjects in MMF arm and 19 in placebo arm completed 6 months study duration. Mean change in FVC was $-1.79 \pm 7.32\%$ in MMF arm and $1.34 \pm 4.47\%$ in placebo arm. Mean absolute difference in FVC change from baseline to 6 months between the two arms was 3.13% (95% CI, -1.02 to 7.28 ; $p=0.131$). In mITT analysis, 15 subjects improved/stabilised and 5 subjects worsened in MMF arm compared to 19 and 2 subjects respectively in placebo arm. SF36v2 scores showed significant improvement in both the groups. No significant difference was noted between the two groups in mean change in focal score of MDI (3.33 vs 2.79; $p=0.638$), DLCO (2.46% vs 2.31%; $p=0.412$), 6MWD (2.8 m vs 12.11 m; $p=0.522$) and FVC among subjects with Scl-70 positivity (-2.19% vs 1.51% ; $p=0.184$). The MRSS decreased by a mean of 4.73 points in MMF arm compared to 1.53 points in placebo arm ($p=0.042$). MMF was well tolerated and rates of diarrhoea and infections were similar to that with placebo. Three subjects on MMF and 1 on placebo discontinued drugs.

Conclusions: In this small study, MMF for 6 months was not effective in stabilising the lung disease in early and mild SSC-ILD but was effective in controlling skin disease and was well tolerated.

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Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.4673

FRI0446 INITIAL PREDICTORS FOR MORTALITY IN PATIENTS WITH CANCER-ASSOCIATED MYOSITIS: A MULTICENTER RETROSPECTIVE COHORT IN JAPAN

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Background: Concomitant malignancy is one of the prognostic factors in patients with myositis,¹ but clinical parameters for mortality still remain unknown in patients with cancer-associated myositis (CAM).

Objectives: Initial predictors for mortality were examined using a multicenter cohort of CAM patients.

Methods: This retrospective study enrolled 67 consecutive patients diagnosed as having CAM in 3 referral hospitals between 1995 and 2017. Clinical data at diagnosis of myositis as well as treatment regimens and outcomes of myositis and malignancy were collected by review of medical charts. Myositis-specific autoantibodies (MSAs) were comprehensively detected using RNA immunoprecipitation (IP), enzyme-linked immunosorbent assay, and IP-immunoblotting. We initially conducted a univariate analysis to select variables that were different between survivors and dead cases. In multivariate analysis, the Cox proportional hazard model with backward selection method ($p > 0.20$) was employed to identify factors independently associated with mortality. Explanatory variables were chosen

based on the following three models. The Model 1 included age at diagnosis of myositis, gender and candidate variables ($p < 0.1$) selected by the univariate analysis. The Model 2 included age, gender, prognostic factors previously reported in myositis, such as dermatomyositis, dysphasia, interstitial lung disease (ILD), anti-ARS, and anti-MDA5, and malignancy type and staging, as explanatory variables. In the Model 3, age, gender, disease duration before diagnosis of myositis, period between diagnosis of myositis and tumour, myositis classification, MSAs, dysphasia, ILD, myositis disease activity after treatment, and malignancy type and staging were used as explanatory variables. Cumulative survivals calculated using the Kaplan-Meier method were compared between the patients with and without risk factors.

Results: The median age at diagnosis of myositis was 63 years, and 62% were female. MSAs were detected in 47 patients: anti-TIF1- γ in 27, anti-ARS in 6, anti-MDA5 in 5, anti-Mi-2 in 3, anti-NXP2 in 3, anti-SAE in 2, and anti-SRP in 1. During the median observation period of 2 years, 19 (28%) of 67 CAM patients were dead due to tumour in 16, ILD in 1, and an unknown cause in 2. The univariate analysis identified significant poor prognostic factors ($p < 0.1$) as follows: male ($p=0.04$), elder age at diagnosis of myositis ($p=0.08$), longer period between diagnosis of myositis and tumour ($p=0.07$), absence of breast cancer ($p=0.001$), malignancy stage III/IV ($p=0.006$). In multivariate analysis, male (HR 8.1, 95% CI 2.6–25.2; $p < 0.001$) and malignancy stage III/IV (HR 12.1, 95% CI 3.3–44.9; $p < 0.001$) were identified as independent risk factors for mortality in the Model 1, and identical variables were identified in the Models 2 and 3. Cumulative survival rates of patients with 0, 1, or 2 risk factors were 100%, 93%, and 69% at 1 year, and 100%, 82%, and 0% at 3 years, respectively. Cumulative survival rates were statistically different between the groups stratified by the number of risk factors (figure 1).

Abstract FRI0446 – Figure 1. Cumulative survival rates of patients with CAM with 0, 1, or 2 or risk factors.

Conclusions: Male and progression of malignancy at diagnosis of myositis were identified as predictors of survivals in CAM patients.

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Disclosure of Interest: H. Kadota: None declared, T. Gono: None declared, Y. Yamaguchi: None declared, E. Watanabe: None declared, Y. Okazaki: None declared, Y. Nakajima: None declared, S. Kobayashi: None declared, Y. Shirai: None declared, M. Takeno: None declared, C. Terai: None declared, M. Kuwana: Grant/research support from: Astellas, Speakers bureau: Astellas and Japan Blood Products Organisation

DOI: 10.1136/annrheumdis-2018-eular.4042