Use of immunosuppressants and clinical outcomes among patients with systemic sclerosis and systemic sclerosis-associated interstitial lung disease: a US cohort study

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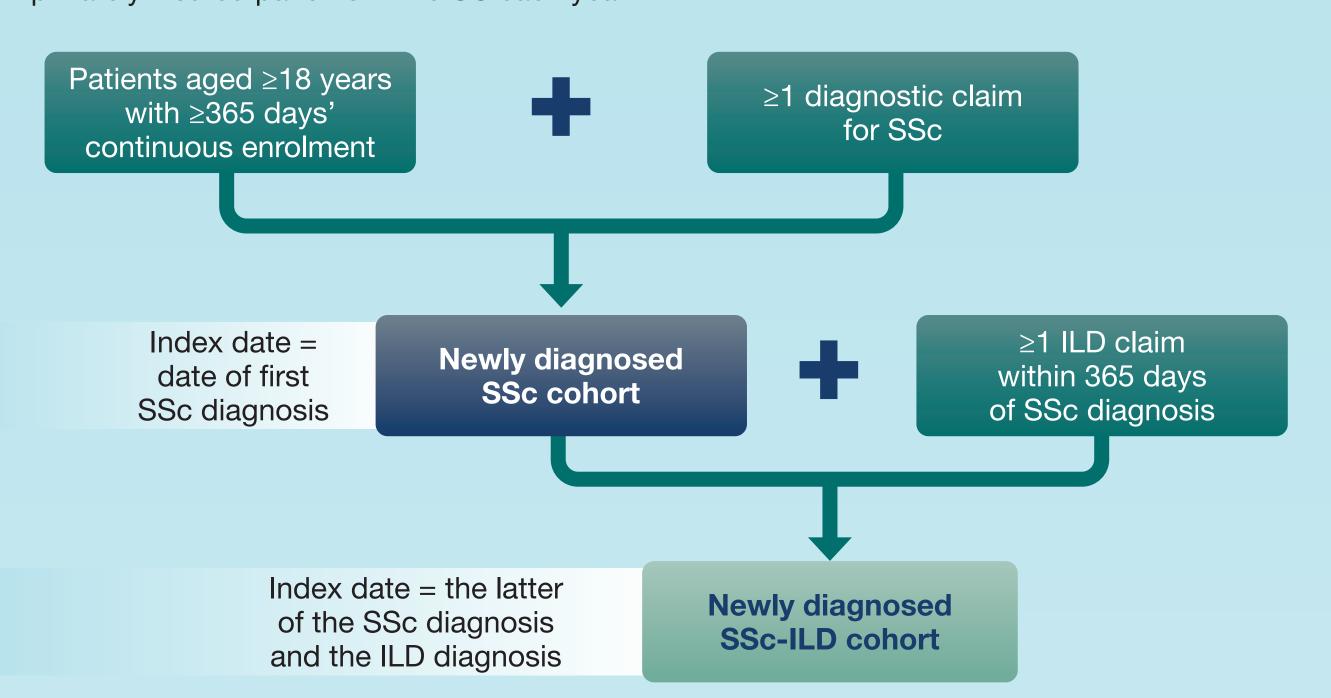
OBJECTIVES

- To investigate incidence rates of clinical outcomes in patients with SSc and SSc-ILD in the US MarketScan® claims database
- To investigate use of immunosuppressive treatments (ISTs) and/or dose escalations in patients with SSc and SSc-ILD in the US MarketScan® claims database

STUDY DESIGN

US IBM® MarketScan® claims database (2008–17)

De-identified outpatient, inpatient and pharmaceutical claims of approximately 45–50 million privately insured patients in the US each year





Follow-up period was from the

- index date to the earliest of:
- Disenrolment from the health plan
- Death
- End of study period



Incident clinical outcomes

Defined as a new claim for a clinical outcome during follow-up among patients who did not have the event in the 365-day baseline period



Definition of dose escalation Following ≥6 months' stable IST regimen:

- Dose increase
- Switching IST
- Adding an IST



Initiation of immunosuppressants defined as initiating ≥1 of the following during follow-up:

- Cyclophosphamide
- MMF
- Azathioprine
- Rituximab
- Methotrexate
- Tocilizumab Tacrolimus
- Cyclosporine
- Anti-tumour necrosis factor drugs

Descriptive analyses of IST course and outcomes during follow-up used Aetion Evidence Platform[™] (v3.12)

RESULTS

CLINICAL OUTCOMES DURING FOLLOW-UP



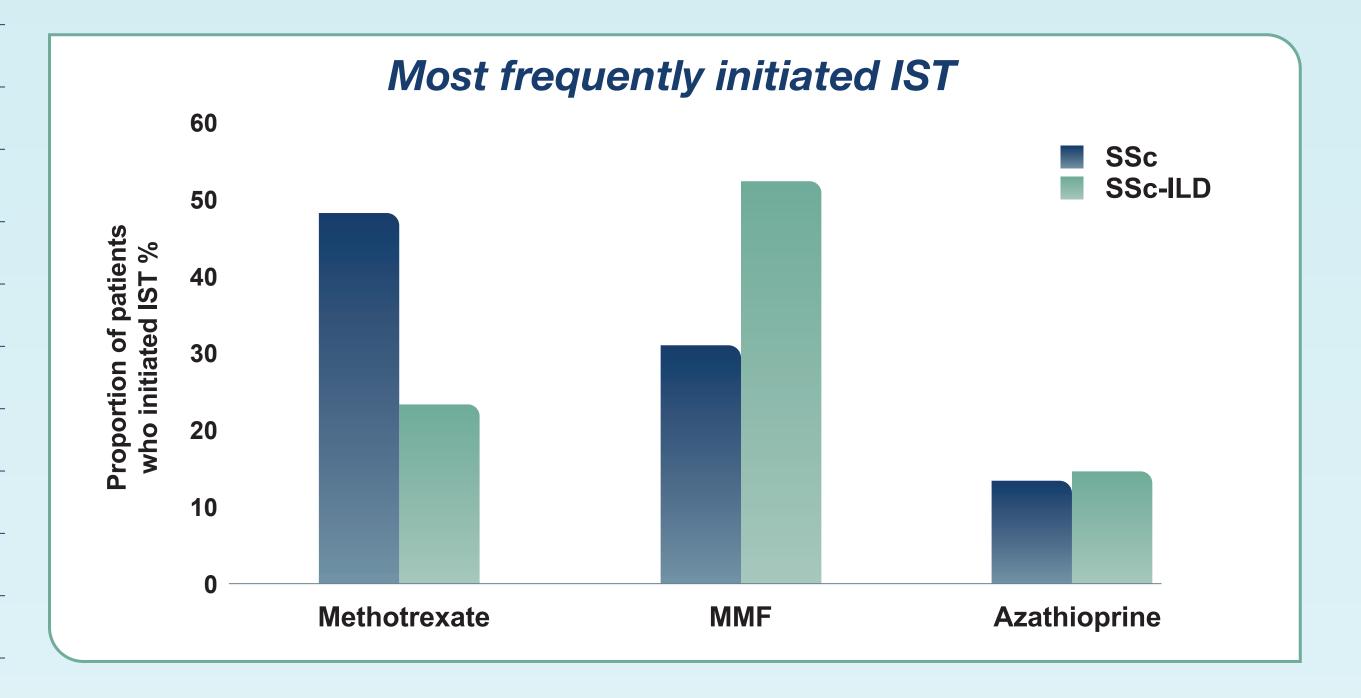
Higher rates of clinical outcomes including gastroesophageal reflux, arterial hypertension, COPD, Raynaud syndrome and pneumonia in SSc-ILD versus SSc

	SSc (n=34,820) ^a	SSc-ILD (n=8,252) ^a
Clinical outcome, IR per 100 person-years (95% Cl)		
Skin disorders	20.3 (19.9, 20.8)	23.3 (22.2, 24.4)
Gastroesophageal reflux	14.4 (14.1, 14.7)	22.6 (21.6, 23.6)
Arterial hypertension	6.1 (5.9, 6.3)	11.1 (10.5, 11.7)
COPD	4.2 (4.1, 4.4)	10.8 (10.1, 11.4)
Raynaud syndrome	6.8 (6.6, 7.0)	9.9 (9.3, 10.5)
Pneumonia	3.2 (3.1, 3.4)	9.7 (9.2, 10.3)
Chronic and acute renal failure or insufficiency	4.2 (4.1, 4.4)	7.8 (7.4, 8.3)
Pulmonary hypertension	2.7 (2.6, 2.9)	8.3 (7.8, 8.8)
Upper respiratory tract infections	6.3 (6.1, 6.5)	6.8 (6.4, 7.3)
Cardiac arrythmia	4.2 (4.1, 4.4)	7.5 (7.0, 8.0)
Urinary tract infections	4.7 (4.5, 4.8)	6.3 (5.8, 6.7)
Bleeding	3.8 (3.7, 4.0)	5.9 (5.5, 6.3)
Lower respiratory tract infections	1.8 (1.7, 1.9)	3.2 (2.9, 3.4)
Lung transplant	0.1 (0.1, 0.1)	0.5 (0.4, 0.6)

^aThe number of patients at risk was defined per outcome as those without the event previously occurring during the 365-day baseline period.

IST initiation in newly diagnosed SSc and SSc-ILD

	SSc	SSc-ILD
	30,088 IST-naïve patients	6,320 IST-naïve patients
Proportion that initiated IST (self-administered)	8.2%	12.7%
Median time after diagnosis	145 days	115 days



Duration of stable IST regimens and time to escalation of IST SSc 436 days 397 days 88 days **289 days** Second stable regimen First stable regimen n/n with sufficient follow-up **First** Second **IST** initiation escalation escalation **First** Second **First** Second stable stable escalation escalation regimen regimen SSc 850/2,002 184/850 86/141 15/86 SSc-ILD 451 days 7/29 294/653 57/294 SSc-ILD 29/44 291 days 87 days 365 days First stable regimen Second stable regimen Second **First IST** initiation escalation escalation

CONCLUSIONS

In this large database, over an average of ~2 years' follow-up:

- More patients with SSc-ILD initiated IST, and they initiated it ~1 month sooner than those with SSc, though duration of stable **IST** was similar
- Preferred IST was different: patients with SSc-ILD were more likely to be treated with MMF, while patients with SSc were more likely to be treated with methotrexate
- Patients with SSc-ILD had a higher IR of clinical outcomes than patients with SSc



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CI, confidence interval; COPD, chronic obstructive pulmonary disease; ILD, interstitial lung disease; IR, incidence rate; IST, immunosuppressive treatment; MMF, mycophenolate mofetil; SSc, systemic sclerosis.

Disclosures

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Relationships and activities

QL is an employee of Boehringer Ingelheim (China) Investment Co., Ltd. LW, PP and VK are employees of Boehringer Ingelheim Pharmaceuticals, Inc. MA and CR are employees of Boehringer Ingelheim International GmbH. MG is an employee of Boehringer Ingelheim (Schweiz) GmbH. JRW and EMG are full-time employees of Aetion, Inc. with stock options; Aetion was contracted by Boehringer Ingelheim International GmbH and authorship of this poster was performed in kind.

