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Original Article

Recombinant human hyaluronidase-facilitated subcutaneous immunoglobulin (hf-SCIg) for inflammatory myositis: a multicenter retrospective real-world observational study

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ABSTRACT

Background: Subcutaneous immunoglobulin (SCIg) is a promising alternative to intravenous Ig (IVIg) for the treatment of idiopathic inflammatory myositis (IIM), thanks to its more favorable safety profile, reduced costs, and lower impact on patients' quality of life. We assessed the short- and long-term effectiveness and safety of recombinant human hyaluronidase-facilitated SCIg (hf-SCIg) in patients with IIM treated at different referral centers in Italy.

Methods: A multicenter, retrospective, real-life cohort study was conducted on consecutive adult patients diagnosed with IIM according to the EULAR/ACR criteria, treated with hf-SCIg for remission induction or maintenance. Hf-SCIg effectiveness was assessed in terms of variation in the Medical Research Council (MRC) score, serum creatine kinase (CK) values, clinical disease manifestations and daily prednisone dosage. Safety data were also collected.

Results: Twenty-six patients with IIM treated with hf-SCIg for remission induction ($n = 5$) or maintenance ($n = 21$) were included in the study (18 females; median age at diagnosis of 59 (IQR 42–64) years)). In most patients, hf-SCIg was started following previous IVIg treatment (23, 89 %) and was initiated in combination with oral corticosteroids (21, 81 %) and/or traditional or biologic DMARDs. Short-term use of hf-SCIg for remission induction appeared associated with a corticosteroid-sparing effect, without worsening of MRC score. Long-term hf-SCIg treatment for up to 24 months maintained clinical stability and serum CK levels with further improvement of MRC score. Hf-SCIg was well tolerated, with mild adverse events mostly related to local site reactions.

Conclusions: Hf-SCIg seems effective and safe for induce and maintain clinical remission in patients with IIM.

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1. Introduction

The spectrum of idiopathic inflammatory myositis (IIM) includes a heterogeneous group of diseases that share chronic inflammation of skeletal muscle, mainly characterized by proximal muscle weakness [1]. Systemic organ involvement can be present, with skin, joints, lungs, esophageal and heart being frequently involved, thus contributing to morbidity and mortality.

Conventional treatment for IIM is based on glucocorticoids and immunosuppressants, including traditional disease-modifying anti-rheumatic drugs (DMARDs, mainly methotrexate, azathioprine, and mycophenolate mofetil) and biologics (mostly rituximab), alone or in combination with DMARDs [2,3].

Intravenous immunoglobulin (IVIg) first emerged as a promising corticosteroid-sparing treatment for refractory/relapsing diseases almost 30 years ago and have been largely used, both for remission-induction and long-term remission maintenance [2–4]. More recently, IVIg has increasingly been used as a first- or second-line therapy, alone or in combination with glucocorticoids [2,5]. However, long-term use of IVIg presents many limitations and it is not always a feasible option. First, IVIg requires intravenous route and in-hospital drug administration, that negatively impact patient's quality of life. IVIg increases the risk of systemic adverse effects (e.g., headache, nausea/vomiting, aseptic meningitis) and the thrombotic risk in adult patients with chronic inflammatory diseases [5,6]. Thus, administration of subcutaneous Ig (SCIg) by a programmable pump has been considered as a possible alternative to IVIg, given their more favorable safety profile, reduced costs, and lower impact on quality of life. To date, the efficacy of SCIg has been reported in primary and secondary immunodeficiencies and in immune-mediated neurological disorders [7–10]. Few data exist about the effect of SCIg in myositis. A case series of seven patients with myositis treated with SCIg showed a decrease in creatine kinase (CK) levels and improvement in muscle strength and quality of life, along with corticosteroid and DMARDs-sparing effect [8]. Moreover, a retrospective study on 12 patients with IIM and 11 patients with chronic dysimmune peripheral neuropathies treated with SCIg provided reassuring results on drug tolerability with positive impact on the quality of life [11].

Since the extracellular matrix limits subcutaneous bulk fluid flow, the amount of SCIg that can be administered in a single injection is low, and therefore the treatment efficacy might be impaired due to drug underdosage. For these reasons, hyaluronidase-facilitated SCIg (hf-SCIg) has been developed. By cleaving hyaluronic acid *via* hyaluronidase, they increase permeability of the subcutaneous tissue, thus allowing the infusion of larger drug volumes [12]. Hf-SCIg is currently approved for the use in patients with primary immunodeficiencies, while its efficacy and safety in IIMs is limited to a case series of five patients with corticosteroid-refractory severe juvenile dermatomyositis (DM) [13] and of a case report on a patient with IIM [14].

On this basis, we performed a multicenter study aiming at evaluating effectiveness and safety of recombinant human hf-SCIg in patients with IIM treated at different tertiary centers in Italy.

2. Methods

2.1. Study design and participants

A multicenter, retrospective, cohort study was conducted in adult patients diagnosed with IIM and fulfilling the EULAR/ACR classification criteria [15], consecutively referring to six Italian tertiary centers for autoimmune rheumatic diseases. All patients were treated with recombinant hf-SCIg as for routine clinical practice, for either remission induction or maintenance. Patients previously treated with SCIg for other therapeutic indications were excluded. Remission induction was considered for patients with newly diagnosed disease or those with refractory/relapsing disease, defined as a clinical and/or laboratory worsening in two or more consecutive visits; remission maintenance was considered for patients with clinical and laboratory control reported in two or more consecutive evaluations.

The study received ethical approval by local Ethics Committee (Comitato Etico Regione Toscana - Area Vasta Centro; IRB approval n. 21,779, 22/03/2022) and each patient enrolled provided written informed consent for the retrospective inclusion in the study

For each patient, data were retrospectively retrieved from medical charts at the time of hf-SCIg introduction (T0 - baseline) and after 3, 6, 12 and 24 months (T3, T6, T12 and T24 respectively). Timepoints T12 and T24 were considered only for patients treated with hf-SCIg for remission maintenance.

All data were collected using a standardize case report form, developed at the coordinating centre (Careggi University Hospital, Florence, Italy) and shared among all participating centres.

2.2. Data collection and treatment outcomes

At baseline, we collected information related to diagnosis and type of IIM, muscular biopsy when available, clinical indication for starting hf-SCIg treatment (remission induction or maintenance) and previous/ongoing treatment other than hf-SCIg.

The effectiveness of hf-SCIg was assessed based on active clinical manifestations, change in the Medical Research Council (MRC) score and variations in serum CK levels. Moreover, concomitant therapies were analyzed, especially prednisone (or equivalent) daily dosage.

Adverse events (AEs) occurred during hf-SCIg treatment were recorded to assess safety profile. Serious AEs were defined as life-threatening AEs, AEs requiring hospitalization, or leading to death or permanent disability.

2.3. Statistical analysis

Data are reported as median and interquartile range (IQR) for non-normally distributed continuous variables, and as absolute number and percentage for categorical variables. Analyses were conducted only for subjects with available data at the considered timepoint, and total numbers of available observations are reported in the tables. The effectiveness of hf-SCIg was assessed separately for patients treated for remission induction or maintenance.

To assess hf-SCIg effectiveness, we identified three continuous variables with recognized clinical relevance (MRC score, CK levels and prednisone total daily dose) and considering the small sample sizes at the different follow-up timepoints, we reported only descriptive statistics. Analyses were performed using the software Stata, version 14.

3. Results

The final cohort consists of 26 patients: of them, five received hf-SCIg for remission induction and 21 for remission maintenance. Baseline demographic, clinical and therapeutic characteristics of the entire study cohort are shown in Table 1. Most patients were female (69 %), with a median age at diagnosis of 59 (IQR 42–64) years. Around half of the patients (46 %) had a diagnosis of dermatomyositis (DM) or polymyositis (PM) (n = 12), 42 % (n = 11) of patients were affected by anti-synthetase syndrome, whereas the remaining 12 % (n = 3) had a diagnosis of immune-mediated necrotizing myopathy. In two patients the diagnosis was associated with paraneoplastic syndrome. Muscular biopsy was performed in 15 patients.

After diagnosis, most patients received corticosteroids (24, 96 %) and traditional or biologic DMARDs (6 each, 23 %). Twenty-three patients (89 %) had been previously treated with IVIg, mostly for remission induction (13/23, 57 %) (**Supplementary Table 1**).

Therapy with hf-SCIg was introduced after a median time of 2.2 years (IQR 1.0–4.2) after the diagnosis of IIM, at a median monthly dosage of 1.7 g/kg (IQR 1.3–1.9). In three patients among the 21 treated for

Table 1
Demographic and clinical patients' characteristics.

	N (% out of 26)
Demographic features	
Female sex	18 (69 %)
Age at the onset	58 (41–63)
Age at the diagnosis	59 (42–64)
Diagnosis	
Dermatomyositis	8 (31 %)
Polymyositis	4 (15 %)
Anti-synthetase syndrome	11 (42 %)
Immune-mediated necrotizing myopathy	3 (12 %)
Serum autoantibodies profile	
Anti-Nuclear Antibodies (ANA)	
Negative	19 (73 %)
Homogenous	2 (8 %)
Speckled	2 (8 %)
Nucleolar	2 (8 %)
Anticentromere	1
Anti-synthetase Antibodies	
Negative	18 (69 %)
Jo 1	6 (23 %)
Other	2 (8 %)
Anti-Ro Antibodies	6 (23 %)
Anti-Ro 52 Antibodies	2 (8 %)
Other ENA*	1
Compatible muscolar biopsy	14/15 with available biopsy (93 %)
Reason for fSCIg initiation	
Remission induction	5 (19 %)
Remission maintenance	21 (81 %)
Main organ involvement	
Skeletal muscle (± other manifestations)	14 (54 %)
Esophageal (± other manifestations)	11 (42 %)
Cutaneous	3 (11 %)
Adverse event/intolerance to IVIg	1
Other non-medical reasons	4 (15 %)
Ongoing treatment at hf-SCIg initiation	
Oral corticosteroids	21 (81 %)
Prednisone daily dosage, (mg/day)	6 (IQR 3–13)
Traditional DMARDs	16 (61 %)
Biologic DMARDs	6 (23 %)

* 5 missing.

remission maintenance, hf-SCIg was introduced to improve patients' quality of life; in the remaining 18 patients hf-SCIg was introduced due to shortage of IVIg (11 patients), center-related logistic issues (2 patients) and attempt to cost reductions (5 patients).

Muscle involvement was the main reason for introducing hf-SCIg (14, 54 %), followed by upper esophageal involvement (11, 42 %) (Table 1). Hf-SCIg was mostly initiated in combination with corticosteroids (21, 81 %), with a median prednisone (or equivalent) dose of 6 (IQR 3–13) mg/day. Sixteen patients (62 %) received concomitant synthetic DMARDs, and six (23 %) biologic DMARDs.

Treatment with hf-SCIg was administered via subcutaneous infusions every 3 weeks according to the summary of product characteristics at a weight-adjusted dose (medium 1.2 g/kg/month).

In the subgroup of five patients treated for remission induction (Table 2), a trend toward improvement in the MRC score was observed (from 42 (36–48) at T0 to 48 (42–60) at T6). Namely, at T3 the MRC score improved in three patients and remained stable in the other two. At T6, the MRC score further improved in one case, remained stable in three cases, and worsened in one case (from 60 at T3 to 48 at T6, with an MRC score at T0 of 36). At T12, the MRC score improved in one case, remained stable in three patients, and worsened in one (from an MRC score of 36 at T0-T6 to 24 at T12). No difference in CK levels emerged. No difference in the proportion of patients receiving concomitant corticosteroid treatment was noted, although total daily prednisone dose tended to decrease (from 20 (0–37.5) mg/day at T0 to 15 (5–50) mg/day at T6). Concomitantly, an overall improvement of clinical manifestations was observed.

In the 21 patients treated for remission maintenance, hf-SCIg

Table 2
Effectiveness of hf-SCIg treatment for remission induction.

	hf-SCIg beginning	3 months	6 months
N patients with available follow-up data	5	5	5
MRC score	42 (36–48)	54 (42–60)	48 (42–60)
MRC score trend	3 improved, 2 stable	1 improved, 3 stable, 1 worsened	1 improved, 3 stable, 1 worsened
Creatine kinase, U/L	44 (30–152)	55 (25–55)	114 (57–601)
Patients on concomitant prednisone treatment	3 (60 %)	5 (100 %)	4 (80 %)
Prednisone dosage, mg/day	20 (0–37.5)	10 (10–10)	15 (5–50)
Clinical involvement			
Constitutional symptoms	3 (60 %)	2 (40 %)	1 (20 %)
Cutaneous involvement	3 (60 %)	1 (20 %)	1 (20 %)
Pulmonary involvement	3 (60 %)	2 (40 %)	2 (40 %)
Oesophageal involvement	4 (80 %)	1 (20 %)	2 (40 %)

effectiveness was assessed over 24 months of follow-up (Table 3). A trend toward an increase in the MRC score emerged after 3, 6 and 12 months of treatment as compared to baseline (from 48 (36–58) at T0 to 48 (48–60) at T12). Namely, 7/17 patients improved their MRC score at T3 compared to T0, other four patients improved at T6 compared to T3 or T0, and other three patients further improved at T12 compared to the previous timepoints.

Serum CK progressively declined during hf-SCIg treatment, from 216 (73–354) U/L at T0 to 150 (82–272) U/L at T24. The proportion of patients receiving concomitant corticosteroid treatment did not change during follow-up, but total daily prednisone dose tended to slightly decrease (from 5 [5–10] mg/day at T0 to 5 (5–5) mg/day at T12 and 5 (2.5–5) mg/day at T24).

Consistent with these variations, clinical manifestations improved throughout the observational period, especially constitutional and esophageal symptoms (Table 3).

Over 24 months of follow-up, 8/26 patients discontinued hf-SCIg, mostly between T12 and T24. The main reason was disease remission (4/8), followed by inefficacy/relapses (3/8). Four patients experienced non-serious AEs, all related to local site reactions ($n = 5$) or musculoskeletal manifestations ($n = 1$), and only one required treatment discontinuation (Table 4).

4. Discussion

In this study, we assessed in a real-life multicenter study, short- and long-term effectiveness and safety of hf-SCIg in IIM. Main results of our study can be reassumed as follows: i) hf-SCIg is a feasible, beneficial and safe treatment option in patients with IIM, both for remission induction and maintenance; ii) short-term hf-SCIg treatment for remission induction seems to have a corticosteroid sparing effect without worsening the clinical manifestations and MRC score; iii) treatment with hf-SCIg for remission maintenance confers long-term stabilization of serum CK and further improvement in MRC score; iv) long-term clinical benefits of hf-SCIg are confirmed also in patients previously treated with IVIg.

The use of IVIg in IIM is well consolidated, and a recent randomized controlled trial conducted in patients with dermatomyositis confirmed that this treatment is associated with a significant clinical improvement [4]. Nevertheless, a few reports suggest that, in real-life clinical practice, SCIg represents an effective and safe therapeutic alternative for the short-term treatment of IIM [6,7,16,17]. As compared to IVIg, SCIg presents a more favorable safety profile, lower costs, and a better impact on patients' quality of life [11].

Moreover, among subcutaneous formulations, the use of hf-SCIg,

Table 3
Effectiveness of hf-SCIg treatment for remission maintenance.

	hf-SCIg beginning	3 months	6 months	12 months	24 months
N patients with available follow-up data	21	21	20	16	11
MRC score	48 (36–58)	48 (36–60)	48 (36–60)	48 (48–60)	48 (36–60)
MRC score trend	-	7 improved, 10 stable ($n = 17$)	4 improved, 11 stable, 4 worsened ($n = 20$)	3 improved, 12 stable ($n = 15$)	1 improved, 8 stable, 2 worsened ($n = 11$)
Creatine kinase, U/L	216 (73–354)	118 (78–540)	115 (90–200)	110 (94–409)	150 (82–272)
Patients on concomitant prednisone treatment	19 (90.5 %)	19 (90.5)	19 (95 %)	15 (93.8 %)	10 (90.9 %)
Prednisone dosage, mg/day	5 (5–10)	5 (5–10)	5 (5–7.5)	5 (5–5)	5 (2.5–5)
Clinical involvement					
Constitutional symptoms	11 (52.3 %)	11 (52.3 %)	8 (40 %)	5 (31.2 %)	4 (36.4 %)
Cutaneous involvement	9 (42.9 %)	6 (28.6 %)	4 (20 %)	4 (25 %)	3 (27.3 %)
Pulmonary involvement	7 (33.3 %)	7 (33.3 %)	6 (30 %)	3 (18.8 %)	3 (27.3 %)
Oesophageal involvement	8 (38.1 %)	5 (23.8 %)	4 (20 %)	2 (12.5 %)	1 (9.1 %)
Neurologic involvement	9 (42.9 %)	7 (33.3 %)	6 (30 %)	6 (37.5 %)	4 (36.4 %)

Table 4
Safety of hf-SCIg treatment.

	3 months	6 months	12 months	24 months
N patients with available data	26	25	21	12
hf-SCIg discontinuation	1	0	6	1
Reason for fSCIg discontinuation	Adverse event, inefficacy	-	1 cancer progression, 3 improvement/ remission, 2 relapse	1 remission
Adverse drug reaction (ADR)	2	1	1	0
Local reactions (infusion site)	2	1	1	
Musculoskeletal disorders	1	0	0	
Serious ADR	0	0	0	

allows the administration of larger drug volume compared to non-facilitated SCIg, thanks to the action of hyaluronidase which increases subcutaneous tissue permeability [12], thus presenting a notable pharmacologic advantage that should be taken int account in clinical practice.

According to a recent systematic review, off-label SCIg treatment can be successfully used in several IIM subtypes, with a wide clinical improvement of cutaneous manifestations, dysphagia, and muscle strength with corticosteroid-and immunosuppressant-sparing effect [17].

Esophageal or pharyngeal dysfunction occurs in 25–84 % of patients with polymyositis and dermatomyositis and accounts for a relevant burden of morbidity, including aspiration pneumonia, failure to thrive, and cachexia secondary to malnutrition [1–2]. The efficacy of IVIg for dysphagia in patients with IIM has been well documented, with response rates in 71–82 % of cases, but few data exist for the role of SCIg [6]. Danieli et al. already reported a beneficial effect of SCIg treatment in patients with IIM, particularly in terms of skeletal muscle inflammation, cutaneous lesions, and dysphagia and by the means of machine learning identified the scores that best predict a positive response to IVIg and SCIg treatment [18–20].

In line with these considerations, we observed a reduction in the proportion of patients reporting dysphagia, although these results need to be confirmed in larger prospective cohorts.

Hf-SCIg appeared to be well tolerated, both in the short-and long-term treatment, with mild AEs mostly related to local site reactions. Only one patient needed to discontinue hf-SCIg due to AE.

Our study presents some limitations that should be considered. First, given its nature of observational retrospective study, it lacks a control group and predefined effect size and sample size calculation. The lack of a control group is noteworthy, as it prevents the possibility of controlling for spontaneous variations in disease activity, as well as discriminating against the impact of concomitant medications. Also, heterogeneity in clinical management among different centers could not be investigated and confounding related to practice-based procedures cannot be excluded.

Despite these limitations, our study has the strength of having included an unselected sample of IIM patients, widely representative of the Italian clinical care, providing for the first time clinically meaningful data on hf-SCIg used for remission induction and maintenance in this setting.

5. Conclusions

Taken together, our findings suggest that hf-SCIg could be a potential treatment option for patients with IIM, particularly for remission maintenance, defined by clinical symptoms, muscle strength and serum CK levels, also in those previously treated with IVIg.

Declaration of competing interest

The authors declare they have no conflict of interest.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ejim.2025.05.016.

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