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BACKGROUND

Crioglobulinemic vasculitis (CV) is a both autoimmune and lymphoproliferative disease, clinically benign, sometimes with a severe presentation, but possibly evolving into lymphoma. Mixed cryoglobulins (CGs) are immune complexes that reversibly precipitate when the temperature is lower than 37°C and that consist of IgM with rheumatoid factor (RF) activity. Most CV patients are HCV positive (70-90%) and conversely 40-60% of HCV infected patients produce CGs of whom 5-30% with symptomatic CV. For this peculiarities in the clinical manifestation and in the diagnostic criteria MC remain an elusive disease.

AIM

The aim of this study was to evaluate :

- 1) the diagnostic approach of MC in a wide real life cohort of Italian patients with HCV chronic infection
- 2) clinical profile
- 3) results of DAA treatment of MC in consecutive patients enrolled in PITER framework

METHODS

Total patients of the cohort: 8005

Total evaluated HCV+ patients: 1678 (21%)

771 (46%) tested positive for MC

266 (34%) MC had typical symptoms and were considered as confirmed MCS

496 (66%) patients have asymptomatic cryoglobulinemia (MC-)

907 (54%) patients tested negative for MC (MC-)

A specific questionnaire regarding clinical and laboratory diagnostic approach of MC and related symptoms was applied.

Results of DAAs treatment of HCV chronic infection in patients with MC were also reported.

RESULTS

Centers that considered MC

36% evaluated MC presence routinely

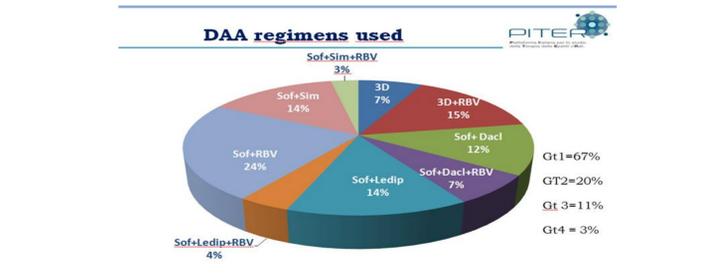
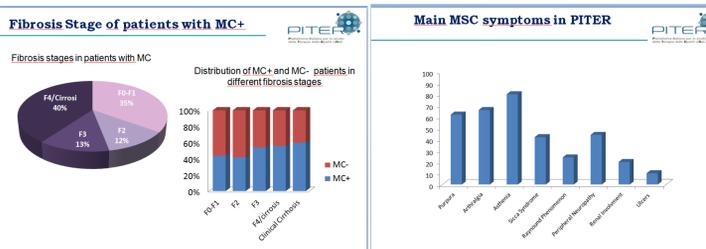
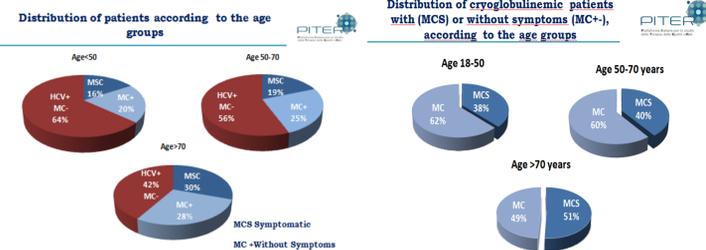
64% following a clinical suspicion

The MC laboratory diagnosis

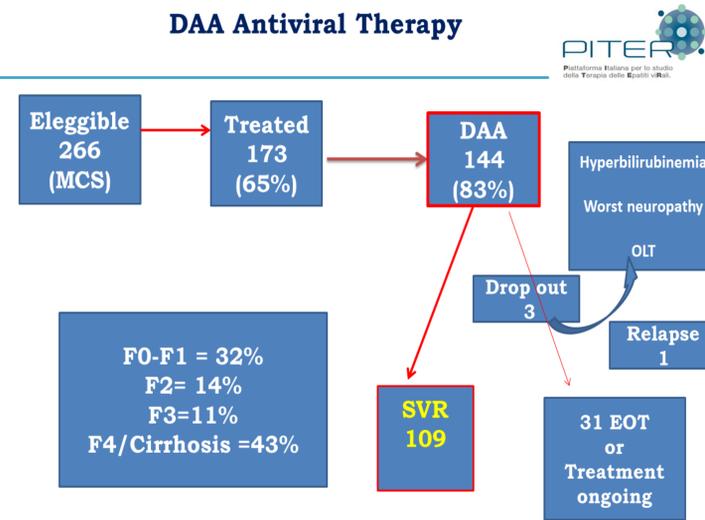
Cryocrit+Complement+RF in 58% of centers

Cryocrit testing only in RF positivity in 42% of centers

Cryo test were non conducted adequately in 39% of centers



DAA Antiviral Therapy



Post Treatment Symptoms in patients achieving SVR12

Disappearance or improvement of all Symptoms in 52 (48%) pts (Complete clinical response)

Improvement of more than 50% of symptoms in 44 (40%) pts (Partial clinical response)

Improvement in less than 50% of symptoms in 10 (9%) pts (No response)

Complete persistence or deterioration in 3 (3%) (No response)

Cutaneous Manifestations (Purpura) were the most rapidly responsive ones

ACKNOWLEDGEMENTS

Authors wish to thank PITER collaborating Group available at www.iss.it/piter for data collecting on a voluntary basis; PITER platform has been supported by Italian Ministry of Health Grant and by un-conditioned partial support from Bristol-Myers Squibb and Merck (MSD Italia).

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CONCLUSIONS

The present, ongoing study, is a the first Italian prospective, multicentric, real-practice analysis conducted on a wide population of HCV-chronically infected patients.

Despite the importance and the clinical relevance, in the Italian real practice, the presence of MC was evaluated only in about 20% of patients.

Among those, the rate of patients carrying CGs is about 46% of whom 34% have typical symptoms.

The variability of MC diagnostic approach, suggesting that the CM presence is underestimated, and in the centers where it is not routinely assessed, the percentage of MC patients showing clinical manifestations is probably overestimated.

In a subgroup of patients treated with DAA that reached the SVR12, the preliminary results showed that: the great majority experienced a disappearance or an improvement of all the baseline symptoms (complete clinical response) or of at least 50% of initial symptoms (partial clinical response). The good clinical and virological results of DAA-based therapy, in this very large, real-life population, further stress the importance of a better appraisal of this condition and consequent wider treatment.