PEDIATRIC RHEUMATOLOGY

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PReS-FINAL-2184: A randomized trial in new onset juvenile dermatomyositis: prednisone versus prednisone plus cyclosporine versus prednisone plus methotrexate

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Introduction

Data regarding the safety and efficacy of treatment regimens for juvenile dermatomyositis (JDM) tends to be from anecdotal, small, uncontrolled, non-randomized case series.

Objectives

To find out the treatment regimen associated with the lowest occurrence of flare and the lowest drug related toxicity in juvenile dermatomyositis (JDM).

Methods

Children with newly diagnosed JDM were randomized in an open fashion to receive: prednisone (PDN) versus PDN plus methotrexate (MTX) versus PDN plus Cyclosporine A (CASA). Primary outcome measures after 6 months of treatment: response rate according to the Paediatric Rheumatology International Trials Organisation (PRINTO) provisional definition of improvement. Primary outcome measures after 24 months of treatment: a) time to inactive disease; b) time to major therapeutic changes because of inefficacy/flare/adverse events; time to flare.

Results

139 randomized patients were included in the efficacy dataset. There were 82 females (59%) with a median age at onset of 7.4 years (1st-3rd quartiles **4.4-10.6**) and a median disease duration of 2.8 months (1.3-5.3). Frequency of response at 6 months was for 24/47 (51%) for PDN, 32/46 (70%) for PDN+CSA and 32/46 (70%) for PDN+MTX (p 0.032).

There was a statistically significant difference for inactive disease/clinical remission between group 3 (PDN+MTX) versus group 2 (PDN +CSA) and 1 (PDN) combined (Log-Rank test p 0.021 and p 0.012, respectively) and in the time to major therapeutic change (defined as the addition of CSA or MTX or any other disease-modifying anti-rheumatic drug) between group 1 (PDN) versus group 2 (PDN+CSA) and 3 (PDN+MTX) combined (p = 0.009). No statistical significant differences in time to flare (Log-rank test; p = 0.39). The safety analysis showed that group 2 (PDN+CSA) had greater number of adverse events (AE) when compared to group 1 (PDN) and 3 (PDN+MTX) (p = 0.005). Similarly there was a statistically significant increase in the frequency of AE in group 2 (PDN+CSA) when compared to Group 1 (PDN) and 3 (PDN+MTX) in several systems (skin and subcutaneous tissues, gastro-intestinal, and general disorders. Infections/infestations) and others (hypertrichosis, hirsutism/hair growth, and abdominal pain). There were no statistically significant differences in serious AE among the 3 groups (p 0.17). There were no deaths.

Conclusion

Combined therapy with PDN and either CSA or MTX was more effective than with PDN alone. However the

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safety profile favors the combination with MTX with respect to CSA.

Disclosure of interest

None declared.

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