MELATHONIN PLUS DANAZOLE, PREDNISONE AND ERYTHROPOIETIN ALPHA IS EFFECTIVE IN TREATMENT OF MYELODYSPLASTIC SYNDROMES WITH ANEMIA AND THROMBOCYTOPENIA.

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BACKGROUND
Melathonin was reported effective in some cases of ITP because of its thrombopoietic effect.

AIM
Aim of this study is to verify if danazole, prednisone, melathonin and erythropoietin alpha is effective and safe in patients with refractory cytopenia with multilineage dysplasia (RCMD) with anemia and thrombocytopenia.

PATIENTS AND METHODS
This study is a multicentric study.
20 patients with RCMD with IPSS intermediate or low showed anemia and thrombocytopenia. Cytogenetics was normal in 15 patients and not evaluable in 5 patients.
In group A 10 patients received orally danazole 200 mg/day, prednisone 25 mg/day, melathonin 60 mg/day, B12 400 mg/day, calcium levofolinate 7.5 mg/day, liposomal iron 30 mg/day, erythropoietin alpha 40000 IU subcutaneous weekly (5 originator and 5 biosimilar) for at least 3 months.
In group B 10 patients received the same treatment except melathonin. In group B 7 patients received originator erythropoietin alpha and 3 biosimilar.
In group A M/F was 6/4, median age was 68 years (R62-80), median follow-up was 4 months (R2-6), median Hb 9 g/dl (R8.5-10), median PLT count 40000/mcl (R30000-50000).
In group B M/F was 5/5, median age was 66 years (R60-84), median follow-up was 3 months (R2-5), median Hb 8.7 g/dl (R8.9-5), median PLT count 27000/mcl (R20000-45000).

RESULTS
In group A median platelet count after treatment was 55000/mcl (R40000-60000), median Hb 10 g/dl (R9-11).
In group B median platelet count after treatment was 38000/mcl (R25000-50000), median Hb 10.2 g/dl (R9-10.5).
In group A the 5 patients receiving biosimilar erythropoietin alpha showed a median platelet count of 55000/mcl vs a median platelet count of 40000/mcl in patients receiving originator molecule.
No side effects were noted in the two group.

CONCLUSION Melathonin, danazole, prednisone and erythropoietin alpha is safe and effective in RCMD with anemia and thrombocytopenia.