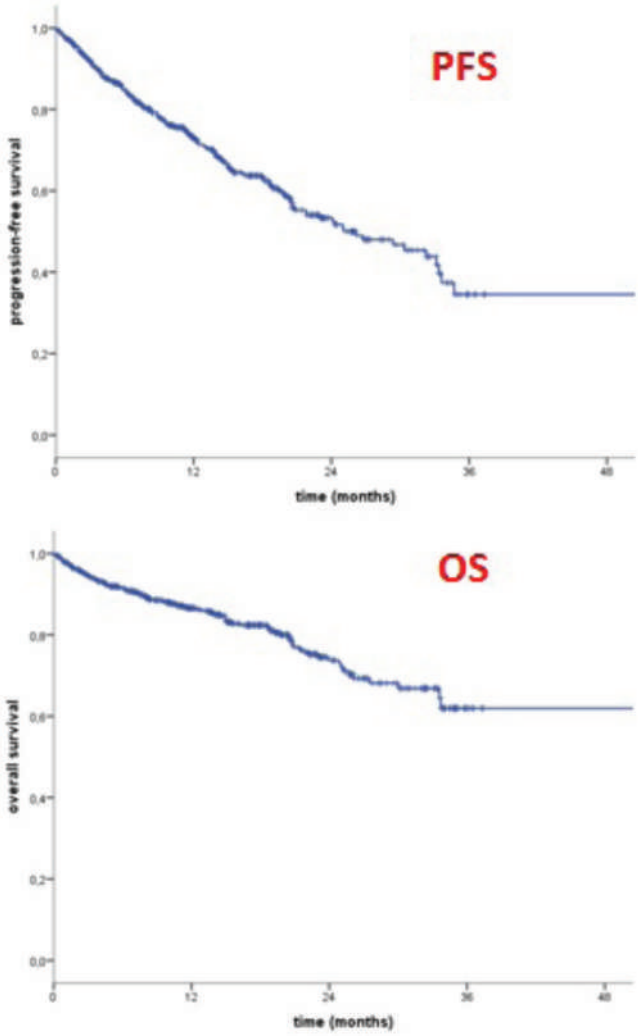
EP1004 LENALIDOMIDE AND LOW-DOSE DEXAMETHASONE (RD) AS FIRST LINE TREATMENT OF NEWLY-DIAGNOSED MULTIPLE MYELOMA PATIENTS NOT ELIGIBLE TO STEM CELL TRANSPLANTATION: REAL LIFE ITALIAN EXPERIENCE

A. Pompa[1*], L. Pettine[1], S. Mangiacavalli[2], M. Galli[3], C. Conticello[4], B. Gamberi[5], E. Antonioli[6], M. Marcatti[7], F. Fioritoni[8], A. Bonalumi[9], A. Belotti[10], D. Derudas[11], S. Pezzatti[12], R. Rizzi[13], P. Bertazzoni[14], D. Vincelli[15], R. Zambello[16], U. Consoli[17], N. Frungillo[18], V. Bongarzoni[19], A. Sementa[20], F. Vozella[21], A. Lombardo[22], F. Guidotti[23], A. Molteni[24], M. Ghentile[25], G. Buda[26], S. Ghentili[27], G. Mometto[28], S. Palmieri[29], A. Gagliardi[30], C. Pasquini[31], F. Cavallaro[1], A. Romano[4], D. Giannarelli[32], V. Mattiello[1], V. Ferla[1], F. Deglinnocenti[1], L. Paris[3], C. S. Cartia[2], T. Perini[7], L. Tognazzi[5], G. Montanaro[8], V. Leotta[4], F. Elia[4], V. Del Fabro[4], C. Bellofiore[4], F. Di Raimondo[4], L. Baldini[1]

[1]Hematology, IRCCS Fondazione Ca'Granda Ospedale Maggiore Policlinico, Milano, [2]Hematology Division, IRCCS Fondazione Policlinico San Matteo, Pavia, [3]Hematology and Bone Marrow Transplant Unit, ASST Papa Giovanni XXIII, Bergamo, [4]Hematology, Azienda Policlinico - OVE, University of Catania, Catania, [5]Azienda Unità Sanitaria Locale – IRCCS di Reggio Emilia SC Ematologia, Reggio Emilia, [6]Azienda Ospedaliera Universitaria Careggi, Firenze, [7]Hematology and Bone Marrow Transplant Unit, IRCCS San Raffaele Scientific Institute, Milano, [8]Department of Hematology, Transfusion Medicine and Biotechnology, "Santo Spirito" Civic Hospital, Pescara, [9]Section of Hematology, Department of Medicine, University of Verona, Verona, [10]Hematology, ASST Spedali Civili di Brescia, Brescia, [11]Struttura Complessa di Ematologia e Centro Trapianto Cellule Staminali Emopoietiche, Cagliari, [12]Hematology and Transplant Department, ASST-Monza San Gerardo Hospital, Monza, [13]Azienda Ospedaliera Policlinico Consorziale BARI, Bari, [14]Hematology Unit, ASST Grande Ospedale Metropolitano Niguarda, Milano, [15]Division of Hematology, Grande Ospedale Metropolitano Bianchi-Melacrino-Morelli, Reggio Calabria, [16]Hematology and Clinical Immunology, Department of Medicine, Azienda Ospedaliera di Padova, Padova, [17]UOC Ematologia ARNAS Garibaldi, Catania, [18]Hematology Unit, ASST Fatebenefratelli Sacco, Milano, [19]Hematology Unit, Azienda Ospedaliera Complesso Ospedaliero San Giovanni - Addolorata, Roma, [20]A.O.R.N. San G.Moscati, Avellino, [21]Division of Hematology, Department of Cellular Biotechnologies and Hematology, Roma, [22]Onco-Hematology Unit Azienda Ospedaliera Santa Maria of Terni, Terni, [23]Hematology Unit, Ospedale Valduce, Como, [24]ASST Cremona, Cremona, [25]Hematology Unit, "Annunziata" Hospita of Consenza, Cosenza, [26]Hematology Division, AOUP Pisa, Pisa, [27]Hematology Unit, Civitanova Marche Hospital, Civitanova Marche, [28]Hematology Unit, ASST Lodi, Lodi, [29]Hematology Unit, A.O.R.N. Antonio Cardarelli, [30] Ospedale S.Maria di Loreto Nuovo, Napoli, [31]Hematology Unit, ASST Crema, Crema, [32]Bio-statistical Unit, Regina Elena National Cancer Institute IRCCS, Roma, Italy

Background: Lenalidomide (Len) and low-dose Dexamethasone (dex) (Rd) in continuous is a new standard of care for elderly newly-diagnosed multiple myeloma (NDMM) patients (pts), showing a remarkable efficacy with a good toxicity profile.
Aims: This is a retrospective, multicentric study conducted in Italy with the aim of evaluating efficacy and tolerability of Rd in a real-life population.
Methods: Thirty-seven centers were involved and data of 509 pts are available. Pts were considered eligible for the study when completing at least 2 cycles of Rd regimen. Data about pts characteristics, response to therapy and safety were collected.
Results: Median age was 77 years (range 40-92), ECOG PS was ≥2 in 36.6% and creatinine clearance was < 50 ml/min in 36.9% of pts. Based on IMWG Frailty score, 18.5, 29.2 and 52.3% of pts were scored as fit, unfit and frail. ISS was I, II and III in 27.5, 39.1 and 33.4% while R-ISS was I, II and III in 32.2, 41.3 and 26.5% of pts. FISH data were available in 48.7% of pts; t(4;14), t(14;16), del(17p) and amp(1q) were respectively found in 8.1%, 4.6%, 5.7% and 35.2%. Extramedullary disease (EMD) was documented in 9.4% of pts. After a median follow-up of 14 months, most pts was still on treatment (55.4%); the median number of administered cycles was 11 (range 2-40). Overall response rate (ORR, ≥PR) was 75.7% with 34.5% of pts obtaining at least a VGPR. Clinical Benefit Rate (CBR, including minimal responses) was 84.3%. Responses were rapid with median time to first (≥PR) and best response respectively of 2.5 (range 1-19) and 6.9 (1-30) months. Median OS and PFS were not reached with 12m and 24m OS of 86.5 and 73.7% and 12m and 24 m PFS of 73.2 and 53.3%. When comparing pts harbouring high risk FISH (i.e. t(4;14), t(14;16) and/or del(17p)) to pts without these abnormalities, ORR was 59.5 vs 79.6% (p = 0.009), without significant difference in terms of 1 year OS and PFS as far (respectively 82.1 vs 91.1%, p = 0.74; 65.3 vs 76.9%, p = 0.41). Dose reduction of Len or dex was required respectively in 23.2% and 22.2% of pts and 39.3% needed cycle delay for adverse events (AEs); 13.1% of pts definitively discontinued Rd for toxicity while 20.8% for progression. Grade 3-4 (G3-4) AEs occurred in 49.9% of pts with 31.4 and 33.6% having at least an hematological or extra-hematological G3-4 AE. In particular, 17.4 and 16.3% of pts had severe neutropenia and anemia while the most common non-hematological AEs were infections (27.2%, G3-4 11%), mainly involving respiratory tract (68.8%). Gastroenteric and cutaneous AEs were quite common (21.4 and 18.9%), but in the vast majority were mild. G3-4 asthenia was present in 21.8% of pts. Although 99% of pts was given antithrombotic prophylaxis, mainly with low-molecular wheight heparin, 8.5% had a thromboembolic event, 37.8% were severe. G-CSF and EPO analogs were required in 26.1 and 27.7% of pts. At the time of analysis, 123 pts (24.2%) had already progressed; 97 pts (78.8% of patients with progression) received a second line therapy, with an ORR of 55.7%. Most used salvage regimens were Bortezomib/Dexamethasone (53.6%) and Daratumumab/Bortezomib/Dexamethasone (21.6%) while 7.1% received only palliation.



Summary/Conclusion: Real-life data in elderly NDMM pts treated with Rd confirm similar efficacy and tolerability registered in randomized clinical trials. Given the availability of FISH data in a large proportion of pts, it will be interesting to evaluate the impact of high risk chromosomal abnormalities after longer follow-up.

EP1005 CLINICAL OUTCOMES AND HEALTH-RELATED QUALITY OF LIFE (HRQOL) AMONG RANDOMIZED CLINICAL TRIAL (RCT)-ELIGIBLE AND RCT-INELIGIBLE PATIENTS: RESULTS FROM THE CONNECT® MM REGISTRY

L. I. Wagner[1*], K. Toomey[2], S. Ailawadhi[3], S. Jagannath[4], C. J. Gasparetto[5], B. G. Durie[6], M. Narang[7], R. M. Rifkin[8], H. R. Terebelo[9], J. L. Omel[10], J. W. Hardin[11], H. C. Lee[12], S. Srinivasan[13], L. Liu[13], M. Dhalla[13], D. Catamero[13], R. Abonour[14]