p < 0,0001, for stage III, II, I,respectively) and in patients with nephrotic syndrome (23,8% vs 3,6%,p = 0,0026,for nephrotic syndrome and asymptomatic proteinuria). Stage III of RI was independent predictor of poor overall survival (OS), but did not impact on renal progression-free survival (PFS). 5-years overall survival was: 61,9%, 71,2 and 51,2% (p = 0.0052), 5-years renal PFS was 90%, 67,7% and 60 % (p = 0,35) for I,II,III renal stage,respectively. Treatments included chemotherapy in 73% (n = 106) and stem cell transplantation 12,5% (n = 18). The median time from treatment initiation to first and best renal response was 7 month (1–68months) and 13,5month (1–69months) respectively. We assessed renal response in 61 patients. In our group of patients, the complete renal response (CR) was achieved in 4,9% cases (n = 3), very good partial response (VGPR) – 42,6% (n = 26), partial response – 32,7% (n = 20). 19,6% (n = 12) have not achieved renal response (NR). OS in patients with CR was 100%, VGPR–88,4%, PR–95%, NR–58,3% (p = 0,0031).5-years renal PFS in patients who achieved renal response was 70,9%.

Summary/Conclusion: Renal involvement and the depth of the response is a prognostically significant factor and a predictor of overall survival and renal survival of patients with MGCS. There is a need for early diagnosis of renal involvement, in order to identify and treat these patients before irreversible organ damage occurs.

PS1418 POMALIDOMIDE-BASED TREATMENT IN RELAPSED REFRACTORY MULTIPLE MYELOMA: ANALYSIS OF BASELINE CHARACTERISTICS AND SAFETY PROFILE OF PATIENTS WHO DIED IN THE EUROPEAN POST APPROVAL SAFETY STUDY

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Background: The immunomodulatory agent pomalidomide (POM) in combination with dexamethasone (DEX) is approved in the European Union for patients (pts) with relapsed or refractory multiple myeloma (RRMM) who were treated with ≥ 2 prior treatment (Tx) regimens, including lenalidomide and bortezomib, and had progressive disease (PD) on the last therapy. POM EU PASS (NCT02164955) is an observational, non-interventional registry designed to characterize the safety profile of POM-based Tx in pts with RRMM in a real-world setting.

Aims: To analyze baseline characteristics and safety profile of POM-based Tx in RRMM pts who died compared with pts who were still alive at the time of data cutoff.

Methods: Pts with symptomatic RRMM starting POM-based Tx were enrolled at investigator's discretion, after providing informed consent. Adverse events (AEs) were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (v4.0). The study is ongoing and open for recruitment in centers across Europe.

Results: As of November 2, 2018, the safety population comprised 638; median follow-up 8.9 mos. At the time of this analysis 346 pts were still alive: 115 pts were undergoing Tx while 155 had discontinued Tx and were in follow-up. A total of 292 pts died, 63 during Tx. Overall, PD (195 pts [66.8%]) was the most common cause of death: 22 pts died during Tx and 173 pts died during follow-up, of whom 146 pts had discontinued POM-based Tx due to PD. During Tx, 38 pts died due to AEs, including infections in 20 pts (8 from pneumonia and 8 from sepsis). During follow-up, 12 patients died due to infections (5 from pneumonia and respiratory tract infections and 6 from sepsis). Except for ECOG PS, baseline characteristics were balanced between pts who died and pts who were still alive (Table 1). Median Tx duration was 15.1 wks (range, 0.6–147.9 wks) for all pts who died, 9.4 wks (range, 0.9–114.3 wks) for those who died on Tx, and 24.6 wks (range, 0.1–172.1 wks) for pts who were still alive. Concomitant cyclophosphamide was administered in 48 pts (16.4%), 6 pts (9.5%), and 53 pts (15.3%), respectively. Grade 3/4 AEs were reported in 226 pts (77.4%) who died, 49 pts (77.8%) who died during Tx, and 208 pts (60.1%) who were still alive. Common grade 3/4 hematologic AEs included: neutropenia (76 [26.0%], 8 [12.7%], and 68 [19.7%] pts), febrile neutropenia (16 [5.5%], 0, and 10 [2.9%] pts), anemia (31 [10.6%], 5 [7.9%], and 30 [8.7%] pts), and thrombocytopenia (29 [9.9%], 4 [6.3%], and 24 [6.9%] pts). Grade 3/4 infections occurred in 97 pts who died (33.2%), 26 pts (41.3%) who died during Tx, and 79 pts who were still alive (22.8%): pneumonia and respiratory tract infections in 18.5%, 17.5%, and 11.3%; sepsis in 2.1%, 4.8%, and 1.4%. Grade 3/4 acute kidney injury was reported in 10 pts (3.4%) who died, 3 pts (4.8%) who died during Tx, and 3 pts (0.9%) who were still alive.

Table 1: Baseline characteristics

Baseline characteristics	Pts Who Died		Pts Who Were Still Alive (n = 346)
	Total (n = 292)	During Tx (n = 63)	
Median age (range), yrs	70 (37-90)	73 (43-90)	71 (43-92)
≥ 75 yrs, n (%)	95 (32.5)	27 (42.9)	121 (35.0)
Male, n (%)	177 (60.6)	38 (60.3)	171 (49.4)
Time since diagnosis, median (range), yrs	4.5 (0.3-25.3)	4.3 (0.3-25.3)	5.0 (0.4-26.9)
No. of previous regimens, median (range)	3.0 (2.0-10.0)	3.0 (2.0-9.0)	3.0 (0-13.0)
≥ 3, n (%)	211 (72.3)	45 (71.4)	250 (72.3)
ECOG PS assessed, n (%)	171 (58.6)	37 (58.7)	203 (58.7)
≥ 2, n (%)[a]	47 (27.5)	18 (48.6)	27 (13.3)

[a] Percentages reported relative to number of pts assessed for ECOG PS.
ECOG PS, Eastern Cooperative Oncology Group performance status; Tx, treatment.

Summary/Conclusion: This analysis revealed a higher proportion of pts with RRMM presenting with an ECOG PS ≥ 2 among those who died during Tx or during follow-up compared with pts who were still alive. In addition, pts who died had a shorter duration of Tx and a higher rate of AEs, particularly infections, than those who were still alive at data cutoff. These findings suggest that pts with a poor ECOG PS at baseline, possibly due to a high disease burden, may develop more side effects during Tx, and therefore, may not be able to tolerate Tx for a long enough duration to derive a clinical benefit.

PS1419 COMPARATIVE EFFECTIVENESS OF TRIPLETS CONTAINING BORTEZOMIB (B), CARFILZOMIB (C), DARATUMUMAB (D), OR IXAZOMIB (I) IN RELAPSED/REFRACTORY MULTIPLE MYELOMA (RRMM) IN ROUTINE CARE IN THE US

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Background: Triplet regimens (TpRs) with a bortezomib-based backbone have traditionally been the most commonly used triplets in RRMM in United States (US). The advent of novel proteasome inhibitors (PIs), immunomodulators (IMIDs), and monoclonal antibodies in MM are rapidly shifting the RRMM treatment paradigm. Lack of head-to-head trials of novel agents versus bortezomib-based triplets used for registration purposes renders treatment choice for RRMM patients (pts) difficult, highlighting a need for real-world evidence.

Aims: To conduct a comparative effectiveness real-world analysis of triplet regimens containing bortezomib (B), carfilzomib (C), daratumumab (D), or ixazomib (I) in RRMM.