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**IXAZOMIB-LENALIDOMIDE-DEXAMETHASONE (IRD) TREATMENT FOR PATIENTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA (RRMM) IN A REAL-WORLD SETTING: PHYSICIAN'S AND PATIENT'S PERSPECTIVE**

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**ABSTRACT**

Evaluation of new treatment regimens in RRMM both from physician's and patients' perspective is worthwhile. The aim of the study was to measure clinical and patient-reported outcomes during IRd treatment as ≥ 2nd line in RRMM pts in a real-world setting.

Adult pts with RRMM who have been assigned IRd as ≥2nd line treatment were enrolled in multicenter observational prospective study. Treatment response was evaluated by IMWG 2011. Pts filled out RAND SF-36 and ESAS-R at baseline and at 1 and 3 mos, and thereafter every 3 mos till 18 mos after IRd treatment start. For statistical analysis GEE was employed with adjustment to age, gender and baseline QoL.

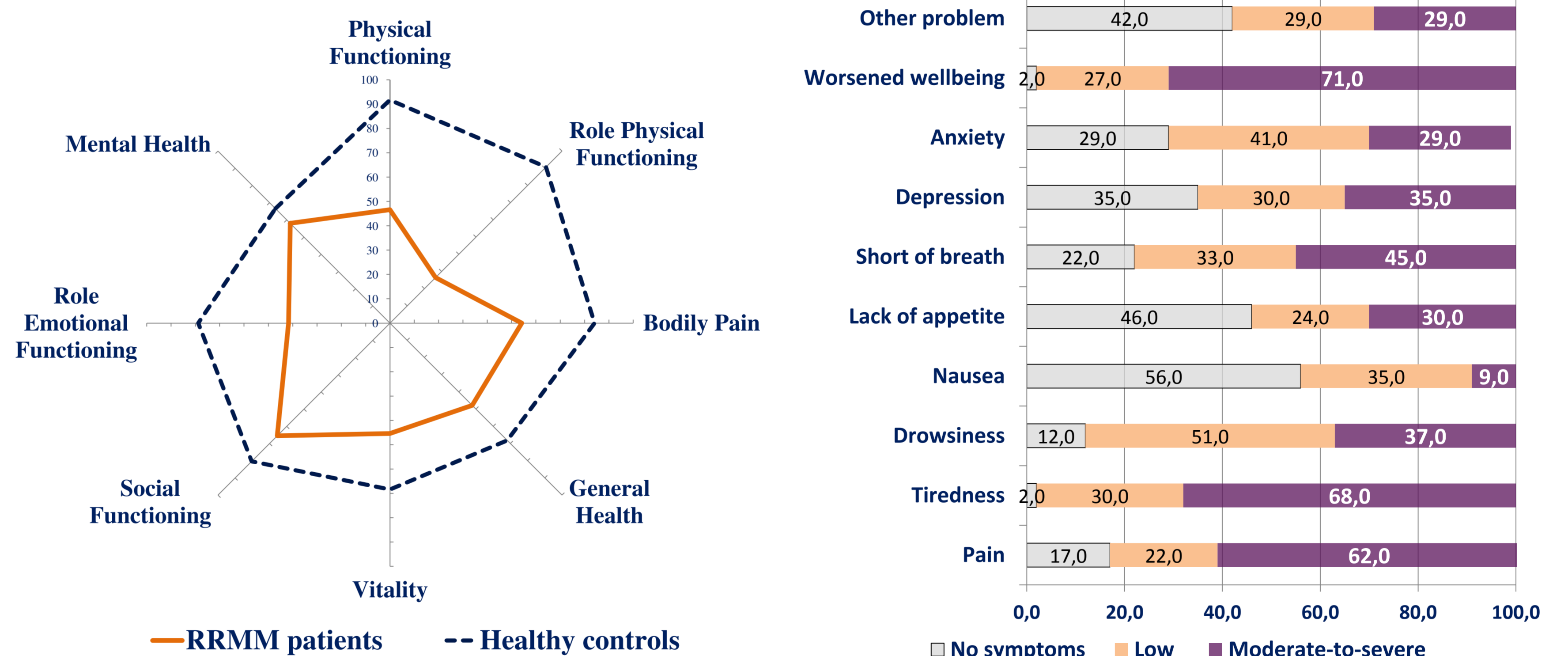
In total, 40 pts with RRMM were enrolled into the study: median age – 64 years (range, 33–80), 29% males, Durie–Salmon stage at study entry: I/II/III – 3/38/58%, ECOG status 0/1 – 68.7%, 2/3 – 31.3%. Median time since initial MM diagnosis – 51.4 mos (range, 2.9–100.7), disease status at study entry: relapsed – 26%, refractory – 21%, relapsed and refractory – 53%. Median number of lines of prior therapy is 3 (range, 1–7). At the time of analysis the median follow-up – 4.4 (0.9-18.1) mos. 26 pts achieved objective response: 2 – complete response, 9 – partial response, 2 – very good partial response, 13 – minor response. Clinical benefit rate – 74%. At the time of analysis 51% pts maintained objective response, 9% had stable disease, 37% progressed. Baseline quality of life (QoL) was dramatically impaired by the majority of SF-36 scales. At baseline 88% pts had moderate-to severe symptoms (≥4 scores on the scale from 0 to 10). During IRd treatment QoL was stable or improved as compared to baseline (GEE, p<0.05); symptom severity meaningfully decreased.

The results obtained in a real-world setting demonstrate benefits of IRd regimen in RRMM pts, both from physician's and patient's perspective.

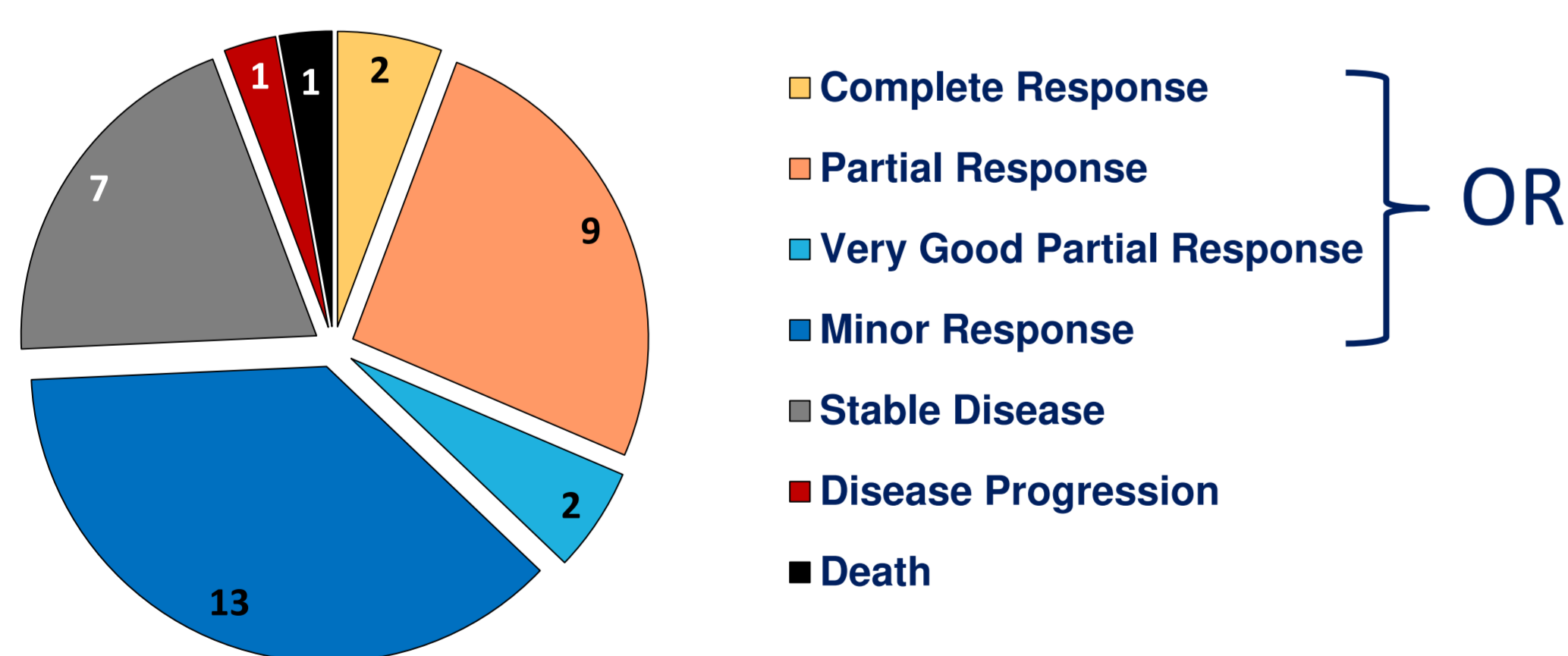
**RESULTS**

Table 1. Patient characteristics	
Median age (Range), years old	64 (33-80)
Male/Female, %	29/71
ECOG PS 0-1/2-3, %	68,7/31,3
Disease duration, median (range), months	51,4 (2,9–100,7)
Stage by Durie–Salmon, %	
I	3
IIA/IIIB	38
IIIA/IIIB	58
No data	1
Disease status at study entry, %	
Relapsed	26
Refractory	21
Relapsed and refractory	53
Comorbidities, %	
No	42,5
Yes	57,5
Median number (range) of previous treatment lines	3 (1-7)

**Baseline QoL and Symptoms**



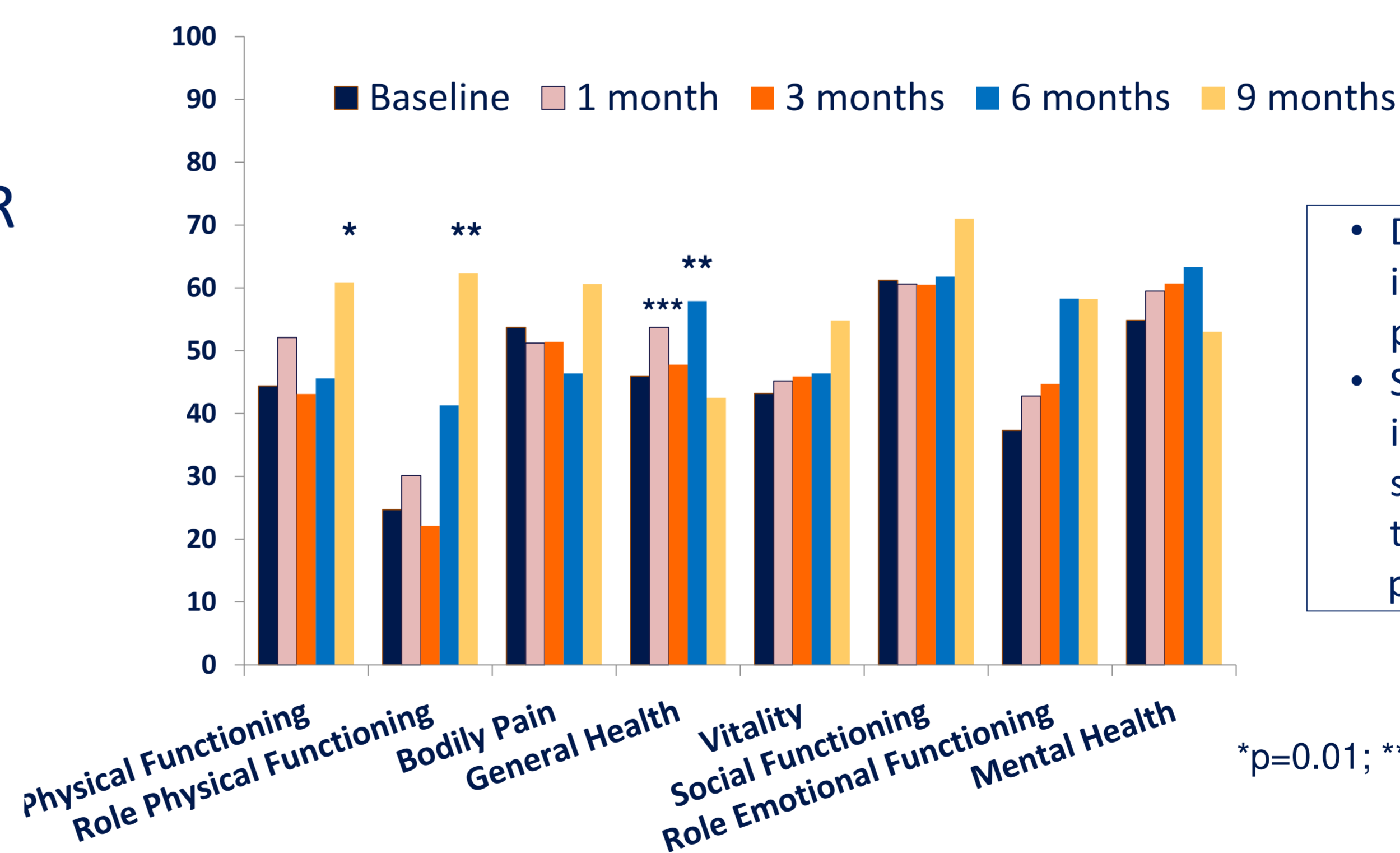
**Treatment Response and Safety**



At the median follow-up 4.4 mo clinical benefit rate – 74%.

AEs were registered in 43% pts:  
• grades 1-2 AEs – 9 pts;  
• grades 3-4 AEs – 4 pts;  
SAEs – 3 pts (neurological toxicity, gastric bleeding, hypotension).

**QoL and Symptoms Changes**



• During IRd treatment QoL was stable or improved as compared to baseline (GEE, p<0.05);  
• Symptom severity meaningfully decreased; in 3 and 6 months shortness of breath significantly decreased in 42% and 33%pts, tiredness – in 36% and 27% pts, pain in 28% and 13% pts.

\*p=0.01; \*\*p<0.01; \*\*\* p<0,0001 as compared to baseline

**CONCLUSION**

The results obtained in a real-world setting demonstrate clinical benefits of IRd regimen in RRMM pts. The treatment has acceptable safety profile and is accompanied with QoL maintenance and satisfactory symptom control in this heavily pretreated patients' cohort.

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