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LENALIDOMIDE: SAFETY AND CLINICAL BENEFIT

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BACKGROUND AND OBJECTIVE

Lenalidomide is a new drug available for haematological malignancies with a very high cost. However data about cost/effectiveness in the clinical practice are still lacking.

Objective: To describe the safety and clinical benefit that lenalidomide treatment yielded in our patients.

METHODS

An observational and retrospective study was conducted including patients who received lenalidomide at some time during the period from 01/07/2010 to 30/06/2011. Indications were multiple myeloma (MM) (labelled indication) or myelodysplastic syndrome with 5q deletion (MDS5q-) (use off-label).

Patients were identified from the electronic register of Pharmacy Department of a 450 beds university hospital.

The variables were: demographic, diagnosis, duration of response, reason to stop treatment, transfusion requirements (MDS), and adverse drug events incidence. The duration of treatment was assumed as a measure of response.

RESULTS

20 patients were included in the study (11 men and 9 women: average age 66 years) with this distribution:

	Multiple myeloma	Myelodysplastic syndrome 5q-
Indication (n)	16	4
Initial dose	25 mg/day	10 mg/day
Need dose reduction (n)	4	2

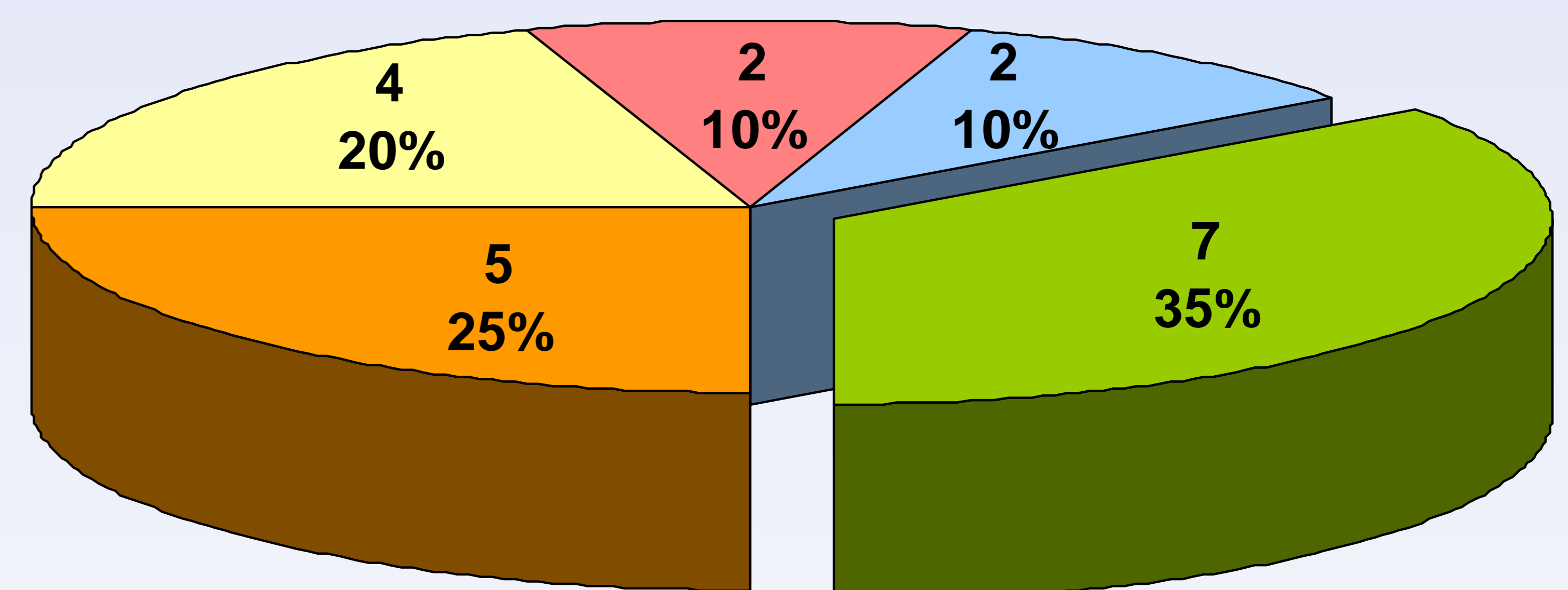
The mean duration of response of patients who completed treatment was 13 months (range: 1-41). For patients who are still on treatment the mean duration is 15 months (range:3-29).

Reasons for discontinuing treatment:

	Multiple myeloma (n)	Myelodysplastic syndrome 5q- (n)
Progression	4	0
Underwent transplantation	1	0
Exitus	4	1
Evolved to acute myeloid leukaemia	0	1

A 65% (13 out of 20) of the patients showed toxicity during treatment.

Adverse effects (AE)



- Hematological toxicity
- Diarrhea
- Not AE so far
- Respiratory infection
- Renal failure

100% of patients with MDS 5q- did not require blood transfusions during treatment.

CONCLUSIONS

In our case series lenalidomide appears to offer acceptable clinical outcomes based on the apparent long average duration of treatment. In the other hand frequent and severe toxicity has led to dose reductions or even patient death. Therefore, the limiting factor for lenalidomide therapy is its toxicity and consequently a closely safety monitoring is mandatory.

17th Congress of

21-23 March 2012,
Milan, Italy