Combination Therapy with Thalidomide Plus Dexamethasone (THAL/DEX) for Newly Diagnosed Myeloma (MM)

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**Type of Session:** Scientific

**Background**

VAD is standard induction chemotherapy for MM patients prior to undergoing stem cell transplant as part of aggressive therapy for this disease.

VAD is cumbersome to administer, requiring central venous access, and also quite toxic, with an associated 27% hospitalization rate.

The dexamethasone component of VAD has been shown to provide 85% of the response seen with the regimen and is an orally administered drug with relatively low toxicity.

Thalidomide has also been shown to have activity as monotherapy against MM.

This study attempts to determine if thalidomide and dexamethasone have efficacy equivalent to VAD as induction therapy for MM.

**Materials and Methods**

This is a phase two study of thalidomide and dexamethasone as MM induction therapy.

Patients received four cycles of THAL/DEX (200 mg thalidomide daily with standard pulse regimen dexamethasone) and were then assessed for response. Eligible patients then received a stem cell transplant. Further cycles of THAL/DEX or conventional chemotherapy were delivered if progression occurred.

Clinical response was defined as > 50% reduction in serum or urine M protein (or 90% reduction if only urine protein was assessed). Minor response was defined as a 25% reduction in serum or urine protein.

50 patients were enrolled in 2000-2001 with a median age of 61. 78% had stage III disease.
Results

Toxicity was low, mostly being grade 1-2 constipation, sedation and rash. 6/50 patients developed DVT which is similar to the risk seen with VAD.

A response was seen in 32/50 patients, similar to that seen with VAD

Only 4 patients progressed and went on to be treated off protocol.

31/50 went on to undergo SCT

38% of those who were anemic prior to induction gained > 2g/dL of hemoglobin

Author’s Conclusions

THAL/DEX is equivalent in efficacy to VAD as induction therapy prior to SCT in newly diagnosed patients with MM and has significantly less toxicity.

A phase III trial evaluating THAL/DEX vs. dexamethasone alone is needed to determine if thalidomide adds efficacy or simply increases DVT risk.

Clinical/Scientific Implications

THAL/DEX is a promising new induction regimen for MM patients prior to SCT. Larger trials may be necessary to determine if it truly is equivalent to VAD. The decreased toxicity of this regimen is encouraging. It remains to be seen if patients treated with this new induction regimen will do as well post SCT as those treated with VAD.

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