PHASE I STUDY OF THALIDOMIDE IN DOGS WITH MALIGNANT TUMORS

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PURPOSE

To perform a phase I trial evaluating adverse events in dogs with malignant tumors receiving thalidomide.

METHODS and MATERIALS

One hundred and eleven dogs with various malignant tumors receiving thalidomide (Talizer, Mexico) were evaluated. The starting dosage was 5mg/kg (group-1) or 10 mg/kg (group-2) PO once daily. In group-1, dose escalation was attempted to 10mg/kg in 7 days unless the adverse effects were clinically significant. Adverse events were evaluated by clinical signs and hematologic toxicities according to VCOG-CTCAE (v1.0) criteria. Only dogs that had a progression of more than 2 grades were included as hematologic toxicities.

RESULTS

Ninety-three and 18 dogs were included in group-1 and group-2, respectively. Nineteen dogs had concurrent chemotherapy and 56 dogs had either NSAIDS or prednisolone with thalidomide. During the dose escalation in group-1, 11 dogs (12%) remained at the same dosage and in 16 dogs (17%) thalidomide was discontinued, due mainly to somnolence. Adverse events were evaluated in both groups. Hematologic adverse events included decrease in Ht (4%), Hb (9.3%), platelets (5.0%) and glucose (3%), and elevation of ALP (6.0%), ALT (23.9%) and total bilirubin (1.5%).

CONCLUSION

Somnolence is the major toxicity of thalidomide but is usually manageable. However, since some dogs experienced significant somnolence, we recommend that the starting dosage of thalidomide be 5mg/kg PO once daily.