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TUMOR-INFILTRATING LYMPHOCYTES (TILS) IN STAGE-I CUTANEOUS MELANOMA - A SOUTHWEST-ONCOLOGY-GROUP STUDY

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## 284 TUMOR INFILTRATING LYMPHOCYTES (TILs) IN STAGE I CUTANEOUS MELANOMA: A SOUTHWEST ONCOLOGY GROUP STUDY. RJ Tuthill, DJ Rector, VK Sondak, PY Liu and FL Meyskens, Jr. The Cleveland Clinic Foundation, Cleveland OH, Southwest Oncology Group Statistical Center, Seattle WA; University of Michigan Medical Center, Ann Arbor, MI; University of California at Irvine, Orange CA.

**Background:** Prognosis in stage I cutaneous melanoma is commonly based upon tumor thickness alone. However, thickness alone is an imperfect predictor of patient survival and there appear to be other factors that have independent predictive validity. Clinical and histologic parameters were evaluated in 259 patients entered into a randomized trial of vitamin A versus observation following excision of primary melanoma (SWOG-8049). Median survival for these patients is 10.8 years (0.6 to 12.1 years). 167 patients are alive (64%) at the time of analysis with 162 patients having at least 5 years follow-up and 73 of these with at least 8 years follow-up.

**Design:** Histologic sections of the primary melanoma were reviewed by one observer (RJT) and the histologic findings were correlated with clinical information. Cox regression analysis using both the univariate proportional hazards model and the multivariate proportional hazards model was used to assess eight characteristics: sex, site, surgery, vitamin A, tumor infiltrating lymphocytes (TILs), histologic regression, mitotic rate and tumor thickness.

**Results:** Tumor infiltrating lymphocytes, mitotic rate, primary site and tumor thickness were found to have independent predictive validity at the 0.05 level of statistical significance. The relative risk of death compared to all patients for each of these characteristics is as follows: absent, slight or non-brisk TILs - 15.1; greater than one mitosis per sq. mm. - 1.97; primary site of head, neck or trunk - 1.81; and tumor thickness > 3.00 mm. - 1.60.

**Conclusion:** 1) there are additional factors in stage I melanoma that have independent predictive validity; 2) patients that lack a brisk lymphocytic host response have 15 times the risk of death compared to those that do have a brisk host response.