Synopsis:

Acute promyelocytic leukemia (APL) has been associated with a significant improvement in survival over the past decade. The largest and most impressive series to date has been published from Italy (the AIDA 0493 trial). There were 107 patients described in this report with a Complete Response (CR) rate of 96%, a 10 year event free survival (EFS) of 76%, and a 10 year overall survival (OS) of 89%.

Unfortunately, this success has come with using increasing doses of anthracyclines. The COG trial is based on the Italian regimen but has been modified to reduce the total anthracycline dosing. Arsenic trioxide and additional high dose cytarabine have been added as they are active agents in APL. This study is being run in parallel to an international pediatric APL trial that has an identical chemotherapy schedule but does not include arsenic trioxide.

Patients will be treated based on their risk factor as determined by white blood cells (WBC) at diagnosis. Patients with a WBC < 10,000/μL at diagnosis are considered standard risk (SR) and patients with a WBC ≥ 10,000/μL are considered high risk (HR). HR patients will receive an additional course of consolidation chemotherapy. Patients will also be monitored for minimal residual disease (MRD) by RQ-PCR for PML-RARA [t(15;17)]. Any SR patient who is RQ-PCR positive at the end of consolidation will receive an additional course of chemotherapy. Both SR and HR patients will receive 2 years of maintenance chemotherapy which is based on European trials using this approach.