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Adjuvant Vinorelbine plus Cisplatin versus observation in patients with completely resected stage 1B-3A non- small cell lung cancer (Adjuvant Navelbine International Trialist Association (ANITA): A randomized controlled trial

Reviewed by Dr. Charles Butts

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This is the final result of the ANITA trial which was a trial of adjuvant cisplatin navelbine chemotherapy in patients with resected stage 1B-3A non-small cell lung cancer. This is another large randomized trial that confirms the benefit of adjuvant cisplatin based chemotherapy. Eligible patients included patients with 1B – 3A disease having complete resection with a WHO performance status of less than or equal to 2. Patients were stratified based on center, stage and histology to receive cisplatin / vinorelbine on a 4 weekly schedule or observation. The study assumed a 2 year survival of 30% of the control group with a 10% absolute improvement in survival with the chemotherapy. 840 patients enrolled in the trial with a median follow-up of 76 months at the time of reporting. 39% of patients were stage IIIA, 24% were stage II and 36% were stage IB. As was seen in other trials, it was difficult to deliver the chemotherapy but particularly so in this trial using weekly vinorelbine over 4 weeks. Only 38% of patients received two thirds of the vinorelbine dose, 63% received two thirds of a planned cisplatin dose. Only 50% of patients completed the planned 4 cycle. Treatment related mortality was 2% which is slightly higher than that seen in the other adjuvant trials such as BR10 or the IALT trial. Results showed significant improvement in survival with chemotherapy with median survival of 65.7 months in the chemo arm versus 43.7 months in the controlled arm p value .017. There was an 8.6 absolute improvement in survival at 5 years which persisted out to 7 years. On sub-group analysis, survival advantage appeared to be limited to those patients with stage II and IIIA disease. There was no difference in survival in patients with stage IB disease. It is important to note that PORT was permitted in this trial. 28% of patients received post-operative radiation, more in the control arm than in the chemo arm. Although this part of the trial was not randomized and was a retrospective analysis, there did not appear to be any negative effect post-operative radiation in the N2 patients that in fact it was suggested there may be a benefit in addition to benefits seen from chemotherapy. This is another trial that confirms the benefit of adjuvant cisplatin based chemotherapy in resected early stage disease. Combined with the results of the BR10 and the IALT trial this further solidifies the role of adjuvant therapy in this setting. In the future, we will refine the most appropriate patients and the best regimen to be used. As seen in the BR10 and the IALT trial there did not appear to be any substantial benefit in the patients with IB disease.